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**UTILITY
PATENT APPLICATION
TRANSMITTAL**

(Only for new nonprovisional applications under 37 CFR 1.53(b))

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| Attorney Docket No. | 47168- 00068USC1 | Total Pages | 36 |
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First Named Inventor or Application Identifier

Keith D. Beaty

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|------------------------|-------------------------------------|
| Express Mail Label No. | EL705448695US, filed August 8, 2000 |
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| APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents. | | ADDRESS TO: Assistant Commissioner for Patents Box Patent Application Washington, DC 20231 |
| <p>1. <input checked="" type="checkbox"/> Fee Transmittal Form (Submit an original, and a duplicate for fee processing)</p> <p>2. <input checked="" type="checkbox"/> Specification [Total Pages 34] (preferred arrangement set forth below)</p> <ul style="list-style-type: none"> - Descriptive title of the Invention - Cross References to Related Applications - Statement Regarding Fed sponsored R & D Invention - Reference to Microfiche Appendix - Background of the Invention - Brief Summary of the Invention - Brief Description of the Drawings (if filed) - Detailed Description - Claim(s) - Abstract of the Disclosure <p>3. <input checked="" type="checkbox"/> Drawing(s) (35 USC 113) [Total Sheets 9]</p> <p>4. <input checked="" type="checkbox"/> Oath or Declaration [Total Pages 2] <ul style="list-style-type: none"> a. <input type="checkbox"/> Newly executed (original or copy) b. <input checked="" type="checkbox"/> Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional with Box 17 completed) <i>[Note Box 5 below]</i> <ul style="list-style-type: none"> i. <input type="checkbox"/> DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b). </p> <p>5. <input checked="" type="checkbox"/> Incorporation By Reference (useable if Box 4b is checked) The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.</p> | | |
| <p>6. <input type="checkbox"/> Microfiche Computer Program (Appendix)</p> <p>7. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary) <ul style="list-style-type: none"> a. <input type="checkbox"/> Computer Readable Copy b. <input type="checkbox"/> Paper Copy (identical to computer copy) c. <input type="checkbox"/> Statement verifying identity of above copies </p> | | |
| <p>Accompanying Application Parts</p> <p>8. <input type="checkbox"/> Assignment Papers (cover sheet & document(s))</p> <p>9. <input type="checkbox"/> 37 CFR 3.73(b) Statement <input type="checkbox"/> Power of Attorney (when there is an assignee)</p> <p>10. <input type="checkbox"/> English Translation Document (if applicable)</p> <p>11. <input checked="" type="checkbox"/> Information Disclosure <input type="checkbox"/> Copies of IDS Statement (IDS)/PTO-1449 Citations</p> <p>12. <input checked="" type="checkbox"/> Preliminary Amendment</p> <p>13. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) (Should be specifically itemized)</p> <p>14. <input type="checkbox"/> Small Entity <input type="checkbox"/> Statement filed in prior application, Statement(s) Status still proper and desired</p> <p>15. <input type="checkbox"/> Certified Copy of Priority Document(s) (if foreign priority is claimed)</p> <p>16. <input checked="" type="checkbox"/> Other Check No. 13194 for \$876.00 ----- -----</p> | | |

17. If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:

Continuation Divisional Continuation-in-part (CIP) of prior application No: 09/232,362

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:) Atty. Docket No.: 47168-00068USC1
)
 Keith D. Beaty) PRIOR APPLICATION:
)
 Application No.: Not Assigned) Examiner: Julian W. Woo
)
 Filed: August 8, 2000) Group Art Unit: 3731
)
 For: Power-Driven Osteotome Tools) Class-Subclass: 606-080.000
 For Compaction Of Bone Tissue)

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Attn: Box Patent Application

Dear Sir:

This application is a continuation of U.S. Application No. 09/232,362, filed January 15, 1999, now allowed.

Prior to examining the subject continuation application, please enter the following amendments.

IN THE SPECIFICATION:

Page 2, line 4, after "This" insert --application is a continuation of Application No. 09/232,362, filed January 15, 1999, now allowed; which--.

IN THE CLAIMS:

Please cancel claims 1-89 and add claims 90-114.

90. A device for developing a bore in living bone, said device comprising:
an osteotome tool having a central axis and a surface for compacting bone;
a driving mechanism including means for interchangeably coupling said driving
mechanism to said osteotome tool, said driving mechanism including a piezoelectric transducer
element imparting a vibrational motion to said osteotome tool; and
a power source for delivering electrical power to said driving mechanism.
91. The device of claim 90, wherein said coupling means includes means for quickly
releasing and attaching said tool from said driving mechanism.
92. The device of claim 90, wherein said vibrational motion is primarily in the direction of
said central axis of said osteotome tool.
93. The device of claim 90, wherein said driving mechanism includes a drive rod between
said piezoelectric transducer and said coupling means.
94. The device of claim 90, wherein said driving mechanism includes a cone-shaped
mechanical coupling component.
95. The device of claim 90, wherein said osteotome tool has at least one segment with a
constant cross-section.
96. The device of claim 90, wherein said osteotome tool has a cross-section that increases
from said lower end to said upper end.

97. The device of claim 90, wherein said coupling means is selected from the group consisting of a spring element, a pin element extending into said osteotome tool, a screw element extending into said osteotome tool, a ball-slot clamping mechanism, a ball-slide clamping mechanism, and a three jaw-chuck device.

98. A method for developing a bore in a living bone, said method comprising the steps of:
providing an osteotome tool having a central axis, a lower end, an upper end, and an engaging surface between said lower and upper ends;
providing a driving mechanism including a piezoelectric transducer element capable of producing vibrational motion;
coupling said driving mechanism to said osteotome tool; and
powering said driving mechanism to actuate said piezoelectric transducer element while engaging said living bone.

99. The method of claim 98, wherein said engaging surface has a sequence of regions from said lower end to said upper end that increase in cross-sectional area.

100. The method of claim 98, wherein said tool has regions of a constant diameter.

101. The method of claim 98, wherein said piezoelectric transducer element oscillates when electrical oscillations are produced by said electrical power.

102. The method of claim 98, wherein said vibrational motion occurs along said central axis of said osteotome tool.

103. The method of claim 98, wherein said vibrational motion has a low amplitude of less than about 1.0 mm.

104. The method of claim 98, wherein said vibrational motion has a frequency of about 500 Hz.

105. The method of claim 98, wherein said vibrational motion is varied by changes to a frequency and an amplitude of electric power supplied to said piezoelectric transducer.

106. A device for developing in living bone a bore that is defined by bone tissue with increased density, said device comprising:

a compaction tool having a central axis, a lower end, and upper end, and a bone engaging surface for displacing bone tissue that is initially in the area defined by said bore primarily in the radial direction with respect to said central axis; and

a driving mechanism including means for coupling said driving mechanism to said tool, said driving mechanism further including means for vibrationally moving said tool.

107. The device of claim 106, wherein said compaction tool is tapered from said upper end to said lower end.

108. The device of claim 106, wherein said vibrational movement is in a direction of said central axis.

109. The device of claim 106, wherein said osteotome tool has at least one segment with a constant cross-section.

110. A method for developing a bore in a living bone, said method comprising the steps of:
providing an osteotome tool having a central axis, a lower end, an upper end, and an engaging surface between said lower and upper ends;
providing a driving mechanism capable of producing reciprocating motion;
coupling said driving mechanism to said osteotome tool; and
engaging said osteotome tool with said living bone, while said osteotome tool is undergoing reciprocating motion.

111. The method of claim 110, wherein said reciprocating motion is in a direction of along said central axis.

112. The method of claim 110, wherein said osteotome tool simultaneously engages said living bone substantially along an entire length of said bore.

113. The method of claim 110, wherein said osteotome tool is tapered from said upper end to said lower end.

114. The method of claim 110, wherein said osteotome tool incrementally compacts said living bone while developing said bore.

115. The method of claim 110, further including the step of developing a pilot hole; and said step of engaging includes inserting said tool into said pilot hole.

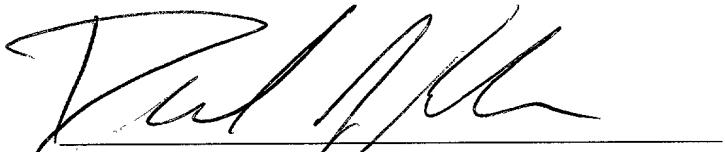
REMARKS

The Applicant has added new claims 90-115. The Applicant believes the new claims are allowable over the prior art of record. Further, the Applicant would like to inform the Examiner that new claim 106 is similar to former claim 87, rewritten in independent form, which the Examiner indicated was allowable in the Office Action dated November 8, 1999, from the parent application.

In view of the above amendments and remarks, the Applicant respectfully submits that the claims now presented in this application are in condition for allowance.

If there are any matters which may be resolved or clarified through a telephone interview, the Examiner is respectfully requested to contact the Applicant's undersigned attorney at the number indicated.

Respectfully submitted,



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Dated: August 8, 2000

PATENT
IMPI:068

APPLICATION FOR UNITED STATES LETTERS PATENT

for

POWER-DRIVEN OSTEOTOME TOOLS
FOR COMPACTION OF BONE TISSUE

by

Keith D. Beaty

| | |
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**POWER-DRIVEN OSTEOTOME
TOOLS FOR COMPACTION OF BONE TISSUE**

CROSS REFERENCES TO RELATED APPLICATIONS

This is a complete application claiming the benefit of copending International
5 Patent Application No. PCT/US97/12512, filed July 17, 1997.

FIELD OF THE INVENTION

The invention relates to an apparatus for preparing a bore in living bone.
Specifically, the apparatus produces a bore in bone via an osteotome or compaction
technique whereby bone is compacted into the side walls and the bottom wall defining
10 the bore instead of being extracted from the bore as is typical during drilling techniques.

SUMMARY OF THE INVENTION

In one embodiment, a combination includes a plurality of tools for insertion into
the bone to produce a bore at a site where an implant is to be installed and a mechanism
for driving those tools. The plurality of tools have portions with the same basic shape
15 but with progressively larger diameters. A set of tools may also include tools having
variable shapes as well. Each tool has surfaces which urge the displaced bone radially
outward and compress the displaced bone into the wall defining the bore. The driving
mechanism can be one of a variety of types including, among many, electromagnetic-
powered devices, hydraulically-powered devices, motor-driven devices, pneumatically-
20 powered devices, and piezoelectric-powered devices.

The tools are coupled to the driving mechanism in series with the smallest being
coupled first. The driving mechanism applies the necessary force to insert the tool into
the bone. The driving mechanism can be operated in various ways. In one embodiment,
the operator continuously moves the driving mechanism toward the bone to engage and
25 contact the tool and to push it further into the bore. Such a driving mechanism has a
portion for engaging the tool that undergoes reciprocating movement to "tap" the tool
into the bore. The tool is not attached to the driving mechanism in this configuration, but
is repetitiously engaged by the driving mechanism.

Alternatively, the driving mechanism includes a shaft that is attached to the tool. The shaft of the driving mechanism causes gradual, steady movement of the tool as it is inserted into the bore. Instead of this gradual movement, this movement imparted on the tool can be incremental or stepped. And, the steady movement can be supplemented by high-frequency vibration to further assist in the insertion of the tools

To further enhance the system, a controller can be used to provide for a more accurate insertion of the tools. For example, the controller may control the depth of insertion, the frequency of reciprocating motion, or the force of insertion.

The driving mechanism may also be modular in that it could be used to insert the dental implant into the bore after the tools have provided the appropriately sized bore. Thus, the shaft of the driving mechanism has means to engage the top portion of a self-tapping implant and screws the implant into the bore. The engaging means may also interface with a tap that is used prior to the insertion of a non-self-tapping implant. Lastly, the engaging means may be coupled to the top portion of a non-threaded implant which is pushed into the bore.

BRIEF DESCRIPTION OF THE DRAWINGS:

FIGS. 1A-1D illustrate a series of osteotome tools having inwardly concave ends;

FIGS. 2A-2D illustrate a series of osteotome tools having outwardly convex ends;

FIGS. 3A-3B illustrate an osteotome tool having an internal fluid channel along its axis;

FIGS. 4A-4D illustrate four progressive insertions of four progressively larger osteotome tools;

FIGS. 5A-5C illustrate clamping mechanisms for coupling the osteotome tool to the driving mechanism;

25 FIGS. 6A-6B illustrate a driving mechanism producing reciprocating motion that
is used to insert the tool into the bone;

FIG. 7 illustrates a solenoid as the driving mechanism;

FIG. 8 illustrates an electric motor as the driving mechanism which produces translational motion through a gear configuration;

FIG. 9 illustrates an electric motor as the driving mechanism which produces translational motion through a cam configuration;

FIG. 10 illustrates an electric motor as the driving mechanism which produces stepped translational motion through another cam configuration;

5 FIG. 11 illustrates a piezoelectric translator driving mechanism;

FIG. 12 illustrates a hydraulically-powered driving mechanism;

FIG. 13 illustrates a dental hand piece driving the osteotome tool; and

FIG. 14 illustrates a power-driven osteotome system with a controller.

DETAILED DESCRIPTION OF THE DRAWINGS.

10 Referring initially to FIGS. 1A-1D, a set of osteotome tools 10a-10d is illustrated. Tool 10a is the smallest and is the first tool to be inserted into the bone. Often, the use of tool 10a is preceded by the use of a small drill that produces a pilot hole. Tool 10a includes an inwardly concave face 12a and a narrow first portion 14a adjacent the concave face 12a. The first portion 14a and the concave face 12a meet at an edge 16a.

15 First portion 14a may be a constant diameter as shown or it may taper outwardly in a direction away from concave face 12a. In a preferred embodiment, the diameter of the first portion 14a is slightly larger (e.g. about 0.2 mm to 1.0 mm larger) than the pilot hole of the bore.

Because the cortical bone is very dense, there is a chance that it could fracture
20 during insertion of the tools. Thus, it may be beneficial to expand the pilot hole at the cortical bone to prevent such a fracture. This expansion can be accomplished through the use of a cutting tool, such as a burr, positioned at the pilot hole prior to insertion of the osteotome tools.

Any bone tissue on the walls defining the pilot hole that is engaged by the edge
25 16a is pushed into concave portion 12a where it collects. In essence, the edge 16a "shaves" off a portion of the bone tissue along the wall defining the pilot hole. When the tool 10a has reached its maximum depth in the bore and is pulled from the bore, the collected material typically remains at the bottom of the bore. Thus, because the edges 16b remove a portion of the bone tissue and the concave face 12b collects this tissue and

displaces it downwardly, the osteotome tool 10a provides a local bone graft. When the osteotome is used in the jawbone, displacing the cancellous bone tissue within the jawbone to the bottom of the bore is advantageous to increase the amount of bone tissue adjacent to the sinus cavity as is described below.

5 Transition surface 18a serves to rapidly force the bone tissue outwardly along the wall defining the bore. Thus, transition surface 18a acts upon the wall to substantially widen it and form a bore of a larger diameter. Because the transition surface 18a is positioned at a distance from the edge 16a of the tool 10a, only a portion of the bore encounters the rapid expansion.

10 Intermediate portion 20a is positioned adjacent to the transition surface 18a. Intermediate portion 20a may be a constant diameter as shown or taper outwardly in a direction way from the concave face 12a. Intermediate portion 20a firms the wall of the bore as tool 10a is inserted into the bore. As with the transition surface 18a, the intermediate portion 20a only engages an axial portion of the bore.

15 A second transition surface 22a is inserted into the bore to further push the walls outwardly near the opening of the bore. This serves to further open the bore at the surface of the bone such that the faces 12b-12d of the next tools 10b-10d can be inserted with ease.

20 A base portion 24a generally does not enter the bore. Instead it is the portion of the tool 10a to which the driving mechanism is coupled as is described in detail below.

In situations where it is desired to widen the ridge of the jawbone, the base portion 24a and, therefore, the second transition surface 22a can be inserted into the upper portion of the bore to begin the ridge-widening process. This ridge-widening process is augmented by the insertion of the tools 10b-10d which have wider diameters.

25 By displacing bone that was once in the central portion of the bore, the transition surfaces 18a and 22a and the intermediate portion 20a also act as local bone grafting tools. This localized bone grafting process provides a bore with a wall having high-density bone tissue.

FIG. 1B illustrates another tool 10b having a slightly larger diameter than tool
30 10a in FIG 1A. The inwardly concave face 12b meets the first portion 14b at edge 16b

which serves to "shave" off an additional section of the wall defining the bore. Transition portion 18b forces the bone tissue outwardly to compact and form a wall with a larger diameter. Again, transition portion 18b provides a substantial widening of the bore as did transition portions 18a and 22a of tool 10a. Intermediate portion 20b
5 compacts the wall as it advances down the length of the bore. There is no second transition portion in tool 10b as there is at reference numeral 22a in tool 10a of FIG. 1A, although there could be. Base portion 24b is the portion to which the driving mechanism is coupled.

Tool 10b also includes a depth mark 26b which indicates the appropriate depth to
10 which the tool 10b should be inserted. The depth park 26b is positioned from the edge 16b of the tool 10b at about the same distance as the transition portion 22a is positioned from the edge 16a of tool 10a. Depth mark 26b typically corresponds to the length of the implant that is to be inserted. As will be seen in FIGS. 1C and 1D, tools 10c and 10d include depth marks at corresponding heights to assist the clinician in determining the
15 correct depth of insertion. Because different bone regions require implants of different length, a different set of osteotome tools can be used that have different lengths and corresponding depth marks. Alternatively, an osteotome tool set may have marks at various depths so that they can be used for implants of various lengths.

The osteotome tools 10c and 10d of FIGS. 1C and 1D are similar to the tools 10a
20 and 10b in that they have inwardly concave faces 12c and 12d and edges 16c and 16d. However, tools 10c and 10d do not include a transition portion. Thus, transition portion 18b of tool 10b is the last surface to quickly expand the diameter of the bore.

The first portions 14c and 14d of these tools 10c and 10d taper outwardly to gradually increase the diameter of the bore as they are inserted therein. The driving
25 mechanism is to be coupled to the base portions 24c and 24d of tools 14c and 14d.

Tool 10c has a pair of depth marks 26c and 28c. Depth mark 26c is at about the same distance from edge 16c as depth mark 26b is from edge 16b in FIG. 1B. Depth mark 28c is approximately at the same distance from edge 16c as the transition portion 18b is from edge 16b in FIG. 2.

Tool 10d includes depth marks 26d and 28d that correspond, respectively, to depth mark 26c and 28c of tool 10c in FIG. 1C. An additional depth mark 30d is positioned near the base portion 26d at a predetermined distance from depth mark 26d.

The concave faces 12a-12d are shown having a smooth, inwardly concave surface. Alternatively, the faces 12a-12d may have a sharp focus point such that the surface is not smooth, or have a back surface that is in a plane that is approximately parallel to the plane defined by edges 16a-16d in tools 10a-10d, respectively.

The osteotome tools 10a to 10d are typically made of a metal such as titanium or stainless steel (e.g. a 400-series stainless steel). Thus, they can be sterilized and reused. 10 Alternatively, the tools 10a to 10d can be made of a polymeric material that can be discarded after each use. The polymeric material must be chosen to provide the necessary strength to allow the cutting action at the edge near the concave face.

Osteotome tools maintain nearly all of the displaced bone tissue within the bore such that only an insubstantial amount is removed therefrom. This is primarily 15 accomplished by the concave faces at the ends of the tool which collect the bone tissue shaved from the walls defining the bore and move that bone tissue deeper within the bore. Additionally, the osteotome tools force the bone tissue radially outward to create a more dense wall. Thus, some of the bone tissue that is in the region that subsequently becomes the bore is displaced radially outward while some of the bone tissue is displaced 20 to a different depth in the bore. Moreover, extraction of the tool has a minimal effect on the bore wall. Consequently, the wall defining the bore is more dense which helps to stabilize the implant within the bore, promote osseointegration, and provide for a more even distribution of stresses onto the walls of the bore caused by the loading of dental components attached to the implant. However, the density of the bone is not made so 25 large that the flow of blood to the bone tissue is substantially inhibited which hinders or possibly precludes the healing process. Instead, the bone density is such that blood flows to the tissue at a rate that promotes the healing of the tissue and osseointegration with the implant.

This osteotome technique is also useful in regions where the bone density is 30 lower than average. This technique increases the density of the bone tissue in these low-

DO NOT SCALE - DO NOT ROTATE

density regions that are immediately adjacent to the bore to a point that is near average, or even above average density. Thus, in low-density regions, an implant placed into a bore produced by this osteotome technique is more stable than one that is placed in a bore produced by common drilling techniques.

5 In a preferred embodiment using the power-driven osteotome technique in the jawbone, the less dense bone, commonly referred to as Type III and Type IV bone tissue, can be compacted such that its density would be comparable to Type I or Type II bone tissue which is usually associated with the more dense cortical plates. However, the compacted bone tissue should not exceed the density of Type I bone. Density values
10 above that of Type I bone could compromise the vascularization and remodeling of the newly packed bone tissue which can lead to a vascular necrosis resulting from inadequate fluid transport across the newly packed region.

Utilizing the osteotome tools 10a-10d also permits the raising of the sinus floor. As the bone is shaved from the side walls, the displaced bone is moved upwardly toward
15 the sinus cavity by the concave faces 12a-12d. This build-up of the bone mass near the sinus boundary elevates the sinus floor, the periosteum, and the membrane layer. Because of the volume of bone located at the bottom of the tools adjacent to the concave faces 12a-12d, the end of the tool typically does not contact the sinus membrane. Instead, the displaced bone tissue engages this membrane. Often, the end of the tool
20 does not penetrate past the original sinus boundary. However, whether the tool engages the membranes depends on the geometry of the concave faces 12a-12d (i.e. the volume of bone which can be contained in that face). If additional bone is needed to elevate the sinus floor, a prepared bone mixture can be added to the bore and pushed upwardly with the shaved bone by the concave faces 12a-12d to provide for additional elevation.

25 Utilization of the osteotome tools produces minimal heat in comparison with common drilling techniques which elevates the local bone tissue temperature due to the high friction at the cutting surfaces of the flutes. Elevated temperatures can damage the bone tissue and slow osseointegration. Thus, the use of the osteotome tools also enhances the quality of the bone tissue adjacent the implant.

FIGS. 2A-2D illustrate another type of osteotome tool 40a-40d. The tools 40a-40d are essentially the same as those shown in FIGS. 1A-1D except that the faces 42a-42d are outwardly convex. This shape is not conducive to carrying bone tissue that is shaved from the sides of the wall. Instead, the outwardly convex faces 42a-42d push the
5 bone outwardly into the wall defining the bore. Because no bone tissue is being shaved from the walls and transported further into the bore, the diameter of the face 42a on tool 40a may be approximately the same or less than the diameter of a pilot hole if one is used. The tool 40a may then taper beyond face 42a to a diameter larger than the diameter of the pilot hole to force the bone tissue radially outward. Although the shape is shown
10 as outwardly convex with a smooth point, it may also be curved with a sharp point. Alternatively, the convex faces 42a-42d may be merely conical in that they come to a sharp point. In yet a further alternative, the outwardly convex faces 42a-42d may have a small dimple at their extremities to displace a small amount of bone tissue inwardly.

FIGS. 3A-3B show yet another type of osteotome tool. In FIG. 3A, osteotome
15 tool 50, shown in bone tissue 52, includes an internal channel 54 in which a fluid (liquid or gas) is carried to the face 56 of the tool 50. The fluid serves to lubricate the bore prior to, or concurrently with, the cutting process that occurs at the edge. The fluid may be an agent which promotes the growth of bone tissue to enhance the osseointegration of the implant around the bore. The channel 54 also assists in removing the collected bone
20 tissue in face 56 in that applying pressure to the channel 54 expels the collected bone tissue from the face 56.

The osteotome tool 60 in FIG. 3B is similar to tool 50 of FIG. 3B except that the internal channel 64 carries fluid not only to the face 66, but to side exits 68a and 68b. Thus, the lubrication can also be provided to the bone tissue 52 at the sides of the tool 60.

FIGS. 4A-4D illustrate the process by which the osteotome tools 10a-10d of
25 FIGS. 1A-1D are inserted into bone tissue 70. In FIG. 4A, the tool 10a is inserted into the bone tissue 70 to a point where second transition 22a meets the upper surface 72 of the bone tissue 70. As stated previously, tool 10a, which has a smaller diameter than the remaining tools 10b-10d, is typically inserted into a small diameter pilot hole. Tool 10b,
30 shown in FIG. 4B, is then inserted until depth mark 26b reaches the upper surface 72.

Tool 10c, shown in FIG. 4C, is inserted until depth mark 26c reaches the upper surface 72 to further expand the bore and provide more compaction of the wall defining the bore. Lastly, tool 10d is inserted into the bore until depth mark 26d reaches the upper surface 72. Tool 10d, shown in FIG. 4D, provides the last compaction of the wall defining the
5 bore prior to the insertion of the implant.

Although the process of FIGS. 4A-4D has been described as using four osteotome tools, the process may require more or less tools depending on the size of the bore that is desired. Additionally, if the diametric difference between successive osteotome tools is kept to a minimum (e.g. less than 0.5 mm difference in diameter), then the amount of
10 force needed to insert the tools is decreased since each tool will be displacing only a small amount of bone. But, this also increases the number of tools required and may increase the overall time required to produce the bore.

Thus far, the osteotome tools and their advantages have been described. FIGS. 5-14 relate to the interaction between the driving mechanism and the osteotome tools. Two
15 basic methods exist for coupling the action of the driving mechanism to the osteotome tools. First, the osteotome tool can be directly attached to the driving mechanism such that any movement, such as vibrational or longitudinal movement, produced by the driving mechanism translates into the same movement of the osteotome tool. And second, the osteotome tool can be engaged repetitiously by reciprocating movement
20 produced by the driving mechanism such that the tool is tapped, or hammered, into the bore.

FIGS. 5A-5C illustrate three methods in which the osteotome tool is coupled to a driving mechanism 80. Each of these methods provides direct attachment of the osteotome tool to the driving mechanism such that any movement by the driving
25 mechanism causes the same movement of the tool. The various types of driving mechanisms 80 will be described in detail with reference to FIGS. 7-14.

In FIG. 5A, the osteotome tool 50 shown in FIG. 3A having internal channel 54 is coupled to a clamping mechanism 90. The clamping mechanism 90 is coupled to a driving mechanism 80 via a shaft 92. The clamping mechanism 90 includes a cylinder
30 94 with an inner wall 96 defining an opening into which the base portion 98 of the tool

50 is attached. A pin 100 extends through a wall of the cylinder 94 and enters a hole 102 in the tool 50. Thus, when the base portion 98 of the tool 50 is inserted into the cylinder 94, it is held captive there by the pin 100. Typically, the pin 100 is biased by a spring 104. Thus, the clinician works against the force of the spring 104 when pulling the pin
5 100 radially outward so as to remove or insert the tool 50.

10 Although the pin 100 is shown extending into the base portion 98 of the tool 50, a pin could be used that extends through the entire base portion 98. For example, a basic cotter pin could be employed which removes the need for the spring 104. In yet another alternative, the pin 100 is replaced by a screw which can be manipulated by hand. The hole 102 then is internally threaded to accommodate the screw. Rotation of the screw causes it to engage the base portion 98 and clamps the tool 50 within the cylinder 94.

15 It should also be noted that the cylinder 94 could simply be a plurality of fingers extending downwardly. One of the fingers must have a width that would allow it to accommodate the pin or screw configurations.

20 To accommodate the passage of fluid through channel 54, the shaft 92 includes a passageway 106 which is coupled to the channel 54 at the top of the base portion 98 of the tool 50. Furthermore, an O-ring 108 acts to seal the interface between the channel 54 and the passageway 106. A fluid supply device (not shown), for example a manual bulb pump or an automatic pump, is coupled to the passageway 106 in the shaft 92 to provide for the flow of fluid through the tool 50.

25 The driving mechanism 80 acts to move shaft 92 in a direction substantially parallel to the axis of the tool 50 such that the tool 50 is pushed inwardly into the bore. As stated previously, the amount of movement of the shaft 92 dictates the movement of the tool 50. The movement of the shaft 92 can be steady such that the tool 50 is inserted at a constant rate. Alternatively, the shaft 92 can be moved downward through incremental, or stepped, movement or the shaft 92 may simply vibrate due to the vibrational energy produced by the driving mechanism 80. After the tool 50 is inserted to the appropriate depth, the driving mechanism 80 is then reversed and the tool 50 is extracted from the bone tissue 70 or the clinician may simply pull the entire assembly
30 from the bore.

The shaft 92 extends into the driving mechanism 80 and moves outwardly therefrom when the driving mechanism 80 is operational. The shaft 92 can also be telescopic such that its portion extending into the driving mechanism 80 does not have to be the same length as the depth of the bore. Consequently, the driving mechanism 80
5 can be designed such that it occupies a smaller volume.

FIG. 5B illustrates a ball-slot clamping mechanism 120, commonly known as a Yankee-style clamp, that is coupled to tool 10d illustrated in FIG. 1D. The tool 10d is shown fully inserted into the bore with the inwardly-concave face 12d containing bone tissue. The ball-slot clamping mechanism 120 includes a cylinder 122 that is attached to
10 shaft 92 of the driving mechanism 80. A platform 124 projects from the cylinder 122. At least one spring 126 is disposed between the bottom side of the platform 124 and a slidable ring 128 that surrounds the cylinder 122. The spring 126 acts on the ring 128 to bias it in the downward direction away from the platform 124.

The ring 128 includes a divot 130 in the shape of a spherical segment. A small
15 sphere 132, possibly a ball bearing, is positioned within an opening 134 in the cylinder 122. The opening 134 is such that the sphere 132 can only partially enter into the cavity of the cylinder 122 and move radially outward into the divot 130. The shape of the divot 130 corresponds to the shape of the small sphere 132 that is positioned against the inside wall of the ring 128.

20 The tool 10d has been modified slightly as it is shown in FIG. 1D to also include a second divot 136 having a shape similar to divot 130 on the ring 128. Also, tool 10d has its upper portion 24d modified such that it can only be inserted into the cylinder 122 in one orientation whereby the first divot 130, the second divot 136, and the opening 134 are aligned. Consequently, the sphere 132 is either partially in the first divot 130 or
25 partially in the second divot 136.

To attach the tool 10d to the ball-slide clamping mechanism 120, the slide 128 is pulled upward from its downwardly-biased position to allow the sphere 134 to enter
30 divot 130 in the slide 128. The tool 10d is then inserted into the cylinder 122. The slide 128 is released such that the spring 126 forces the slide 128 downwardly and the sphere 132 is pushed inwardly by the inner wall of the slide 128. The sphere 132 then is forced

into second divot 136 which locks the tool 10d into position. To remove the tool 10d, the slide 128 is pulled upwardly so that the sphere 132 enters the first divot 130 which frees the sphere 132 from the second divot 136 thereby releasing the tool 10a.

FIG. 5C illustrates a common three-jaw chuck device 150 clamping osteotome 5 tool 40d from FIG. 2D. The three jaws 152 grasp the upper portion of the tool 40d and hold it firmly in place. The jaws 152 fit within a collar 154 which is coupled to a chuck 156. The shaft 92 of the driving mechanism 80 attaches to the upper end of the chuck 156.

When the chuck 156 is rotated relative to the collar 154, the three jaws 152 either 10 spread apart or come together, depending on the direction of rotation. The chuck 156 includes gear teeth 158 at its lower end to which a geared key engages to help rotate the chuck 156 relative the collar 154 to open and close the jaws 152. The collar 154 also includes a hole 160 in which the geared key can be inserted to assist in this task. Thus, the tool 40d can be attached through the clinician's manual rotation of the chuck 156 15 relative to the collar 154 or the clinician can use a key to perform this task.

In FIGS. 5A-5C, the driving mechanism 80 includes the shaft 92 which urges the tool downwardly into the bone. The movement of the shaft 92 and, therefore, the tool can be continuous such that the insertion occurs at a constant rate. Alternatively, the insertion can be stepped in that the shaft 92 moves the tool for a predetermined time 20 interval at a predetermined rate and then stops, or slows, before resuming to that predetermined rate. Thus, the tool is incrementally inserted into the bone.

In addition, the driving mechanism 80 may also include a high-frequency vibration transducer, such as a piezoelectric transducer or an ultrasonic transducer. As the tool is being inserted, high-frequency waves act upon the tool through the shaft 92 to 25 assist in the insertion process. The frequency and amplitude of the waves are selected to provide ease of insertion but preferably produce minimal heat at the interface between the tool and the bone tissue. In one preferred embodiment, the amplitude is low (less than about 1.0 mm) and the frequency is high (e.g. 500 Hz). Thus, less axial force from the driving mechanism 80 is needed to insert the tool into the bone.

FIGS. 6A and 6B illustrate a reciprocating driving mechanism 180 that is inserting tool 10a, shown in FIG. 1A, into bone tissue 70 to form a bore. The driving mechanism 180 includes a shaft 192 which reciprocates an engaging mechanism 194 that is attached to the shaft 192. The engaging mechanism 194 taps, or hammers, the tool 10a into the bone tissue 70. FIG. 6A shows the shaft 192 at the lower end of its stroke as the engaging mechanism 194 contacts the tool 10a. FIG. 6B depicts the shaft 192 at the upper end of its stroke when it is not in contact with tool 10a. Thus, the primary difference between the clamping mechanisms of FIGS. 5A-5C and the engaging mechanism 194 of FIGS. 6A-6B is that the clamping mechanisms remain attached to the tool at all times during operation while the engaging mechanism 194 does not. In the configuration of FIGS. 6A and 6B, it may be necessary to pull the tool 10a from the bore after the driving mechanism 180 fully inserts the tool 10a.

Although the upper portion of the tool 10a has a flat surface, it may have a curved surface to minimize the amount of off-axis tapping causing the angle of insertion of the tool 10a to vary. The inner surface of the engaging mechanism 194 may also include a curved surface. Additionally, the entire engaging mechanism 194 can be a variety of shapes. Thus, it can surround the tool 10a by having an internal cavity, as shown, or it can be a flat surface. Additionally, the base portion 24a of the tool 10a can have a polygonal cross-section with the engaging mechanism having a corresponding socket.

FIG. 7 illustrates a solenoid 200 which is used as the driving mechanism. The solenoid 200 includes an armature 202 which moves between two positions (one showed in dashed lines) when the coil 204 is energized and deenergized. Typically, a spring biases the armature 202 to the deenergized position. Armature 202 would act as, or be coupled to, the shaft 92 or 192 of FIGS. 5-6 to move the tool into the bore.

Typically, the armature 202 moves rapidly between the two positions with transition times being less than about 0.5 second. Thus, it serves as a useful driving mechanism for the reciprocating-type driving mechanism 180 shown in FIGS. 6A and 6B. Thus, energizing and de-energizing the coil 204 produces this rapid reciprocating motion.

Also, the movement of the armature 202 can be designed to produce a slow movement between the two positions. For example, the current through the coil 204 can be slowly ramped-up to produce this slow movement. Alternatively, the armature 202 can be damped by a spring or a hydraulic device to resist, but slowly yield to the electromagnetic force produced by the coil 204. Thus, the solenoid 200 could also serve as the driving mechanism 80 shown in FIGS. 5A-5C.

FIG. 8 illustrates one of many possible meshed gear configurations. In FIG. 8, a pair of beveled gears 230 and 232 drives a worm gear 234 on post 236. A shaft 238 attached to the first beveled gear 230 is driven by an electric motor 240 (AC or DC). As the first beveled gear 230 turns the second beveled gear 232, a worm gear 234 engages internal threads (not shown) within the second beveled gear 232 to move post 236 between the two positions (one shown in dashed lines). Post 236 is coupled to, or acts as, shaft 92 in the driving mechanism 80 of FIGS. 1-5. Another meshed-gear configuration would simply rotate a nut-type structure having internal threads around an externally threaded shaft (like post 236) to cause longitudinal movement of the shaft. One advantage of the gear configuration illustrated in FIG. 8 as well as other meshed-gear configurations is that the depth of penetration could be accurately controlled since there would be a fixed relationship between the penetration depth of the tool and the number of revolutions of the shaft 238 coupled to the electric motor 240.

To produce a rapid reciprocating motion, the electric motor 240 produces oscillatory electrical power to rotate shaft 238 in both directions which, in turn, moves the post 236 in both directions. Thus, the gear configuration of FIG. 8 can also be used to produce the reciprocating motion described with reference to the driving mechanism 180 of FIGS. 6A and 6B.

FIG. 9 illustrates one of many possible cam configurations that produce axial movement of the tool. The electric motor 240, the same as the one shown in FIG. 8, drives cam cylinder 250 via a shaft 241. Cam cylinder 250 has an upper surface 251 near the electric motor 240 and a lower surface 253. The lower surface 253 is, in essence, a cam in that it is irregularly shaped with a cam drop 254.

Member 260 is shown in a exploded view away from cam cylinder 250 but in operation is immediately adjacent the cam cylinder 250. Member 260 includes an upper surface 261 corresponding to lower surface 253 of the cam cylinder 250. A cam drop 262 matches the cam drop 254 of the cam cylinder 250. A spring 264, coupled to member 260, biases member 260 upward to engage the cam cylinder 250. Member 260, which typically does not rotate, also has a post 268 to which it is coupled.

When the electric motor 240 rotates the cam cylinder 250 such that the opposing cam drops 262 and 254 move away from each other, the lower surface 253 of the cam cylinder 250 engages the upper surface 261 of the member 260 forcing member 260 downward against the bias of the spring 264. Consequently, post 268, which is coupled to, or acts as, shaft 92 of the driving mechanism 80 of FIGS. 5A-5C, moves downward. Because the amount of the axial movement of post 92 is the same as the length of cam drop 254, the amount of movement can be accurately controlled. Additionally, if a only portion of the maximum axial movement is needed (e.g. 75%), then the amount of rotation of the cam cylinder 250 is limited to 75% of one revolution (i.e. 270°). Again, the amount of axial movement of post 268 can be accurately controlled. And, the spring 264, which determines the force of insertion, is selected accordingly.

If the reciprocating movement of FIGS. 6A and 6B is desired, the cam cylinder 260 can be rotated continuously. The action of the spring 264 maintains the position of the action member 260 in its upwardly biased position after one full revolution. The frequency of the reciprocating motion corresponds to the angular speed of the shaft 241.

FIG. 10 illustrates the electric motor 240 rotating a cam cylinder 280 that has a small cam 282 on its lower surface. The small cam 282 engages a projecting surface 284 located on a plate 286 attached to rod 288. The plate 286 is biased in the upward position by a spring 290 attached to structure 292. As the cam cylinder 280 rotates, the rod 288 reciprocates between two positions (one shown in dashed lines). To drive the osteotome tool, rod 288 is coupled to, or acts as, shaft 192 of the driving mechanism 180 of FIGS. 6A and 6B.

FIG. 11 illustrates a piezoelectric vibrator 300 which imparts reciprocating or vibrational motion to the osteotome tool. The vibrator 300 includes a transducer element

302 to which is attached two electrodes 304 that are coupled to an electrical source 306. A cone-shaped mechanical coupling component 308 is attached to the transducer element 302 and has an acoustical length that causes it to vibrate when the transducer element 302 is actuated. When electrical oscillations are produced by the electrical source 306,
5 the transducer element 302 oscillates and causes the coupling component 308 to vibrate. A rod 310 affixed to the end of the coupling component 308 then reciprocates between two positions (one shown in dashed lines). Variations in the amplitude and frequency provided by electrical source 306 cause variations in the movement of the rod 310. Thus,
10 rod 310 is coupled to, or acts as, shaft 192 of the driving mechanism 180 of FIGS. 6A and 6B.

The piezoelectric vibrator 300 can also be used to provide high-frequency vibrations. Thus, it can be used by itself, or in tandem with another type of driving mechanism that causes the axial movement of the tool. The piezoelectric vibrator 300 would provide the high-frequency waves while the other driving mechanism would
15 provide the axial movement. As stated previously, the high-frequency waves would assist in the insertion of the tool.

Another device which can provide vibrational movement to the tool is a harmonic generator which is often used to power a scalpel. The harmonic generator provides ultrasonic energy which operates at a very high frequency (i.e. about 50 kHz) in the
20 longitudinal direction of the tool via ultrasonic transducer. Generally, the amplitude applied to the tool when using such a harmonic generator is between 20 and 200 microns. The ultrasonic motion of the tool has extremely high acceleration which converts mechanical energy into thermal energy in a very localized region. The heat associated with this thermal energy can be used to reduce or eliminate some of the bleeding which
25 occurs during the insertion process. The coagulation which results from this motion may be desired in situations where excessive bleeding is a concern since in most cases, minimal heat is desired so as to not damage the bone tissue. One example of a harmonic generator that produces ultrasonic energy is described in U.S. Patent No. 5,026,387 which is herein incorporated by reference in its entirety.

FIG. 12 illustrates a hydraulically-actuated driving mechanism 320 having a cylinder 322 contains a piston 323 that is connected to a rod 324. A pump device 326 acts upon the fluid to move it into and out of the cylinder 320. A fluid accumulator 328 may also be present within the hydraulically-actuated driving mechanism 320. The 5 pump 326 may be a hand pump or powered pump. As the fluid moves into the lower portion of the cylinder 322, the piston 323 moves upward thereby moving rod 324 upward. Thus, rod 324 is coupled to, or acts as, shaft 92 of the driving mechanism 80 of FIGS. 5A to 5C described above. A structure similar to the hydraulically-actuated driving mechanism 320 which works on pressure produced by air or other gases (i.e. 10 pneumatically-actuated system) could be utilized.

FIG. 13 illustrates a driving mechanism 330 which utilizes a common dental hand piece 332. The dental hand piece 332 includes a driving component 334 which oscillates between two positions due to the rotation of a shaft 336. As shown, the shaft 336 is coupled to the driving component 334 by a yoke-type configuration although a gear 15 configuration or cam configuration could work just as well. The shaft 336 is supported within the dental hand piece 332 by a bearing element 337 that is near the driving component 334.

The bottom side of the dental hand piece 332 includes an opening 338 in which a tool 340 can be inserted. The tool 340 is an osteotome tool as described previously 20 which compacts the bone tissue in the bore which it is creating. The tool 340 includes a narrow neck portion 342 above which resides a head portion 343. The tool 340 also includes a ring 345 which prohibits the insertion of the tool 340 beyond a predetermined depth in the bone tissue. In other words, ring 345 is a stop mechanism which engages the exterior surface of the bone tissue thereby allowing only the lower segment of the tool 25 340 below the ring 345 to be inserted into the bone.

The amount of oscillation in the tool 340 is a function of the amplitude A at which the driving component 334 is oscillating. The motion of the tool 340 is also a function of the length L of the narrow neck portion 342. Because the frequency at which the driving component 334 operates is a function of the angular velocity of the shaft 336, 30 the frequency at which the tool 340 oscillates can be controlled. The distance which the

tool 340 travels in one-half cycle (i.e. one path down or up) is a function of the amplitude A at which the driving component 334 operates. Additionally, the distance which the tool 340 travels in one-half cycle is a function of the length L of the narrow neck portion 342 of the tool 340. Thus, the distance the tool travels can be controlled as well. By 5 means of an example, the frequency may be in the range of 500 Hz to 1000 Hz and the distance traveled may be on the order of a millimeter or less.

In FIG. 13, the force F that is being exerted on the driving mechanism 330 and then transferred to the tool 340 is produced by the clinician. Thus, the tool is moving into the bore under the force of the clinician while vibrating at a know rate to assist in the 10 insertion process.

The various driving mechanisms described can provide two types of motion. First, these mechanism can be used to provide oscillatory or vibrational motion to the tool to assist in the insertion of the tool. The primary force to insert the tool would then be the force applied by the clinician to the driving mechanism. Alternatively, the driving 15 mechanism may provide for translational movement to insert the tool to the proper position within the bore. In yet another alternative, the driving mechanism may provide both translation and vibrational energy.

FIGS. 7-13 illustrate various driving mechanisms which could be used to insert an osteotome tool into a bone and create a bore for an implant. Because the 20 characteristics of the movement of the tool (e.g. depth of insertion, the force of insertion, the frequency of insertion, etc.) are important, the operation of the driving mechanism may be controlled by a controller. FIG. 14 illustrates, in block diagram form, a power-driven osteotome system 350. The system 350 includes a controller 360 which is coupled to the drive mechanism 362. The controller 360 applies power to the drive 25 mechanism 362 which, in turn, acts upon the tool 364 to force it into the bone. The drive mechanism 362 may be any type of drive mechanism including those described in FIGS. 7-13 and the tool 364 may be any type of osteotome tool including those described in FIGS. 1-4. The tool 364 is releasably coupled to the drive mechanism 362 through various methods including those disclosed with reference to FIGS. 5-6.

- The controller 360 may monitor the drive mechanism 362. For example, if the drive mechanism 362 includes the electric motor 240 of FIGS. 8-10, the controller 360 may sense an angular displacement sensor, such as an encoder, within the motor 240 to determine the angular position of the shaft of the motor 240. This can be used to
- 5 determine the angular speed which corresponds to the reciprocating movement of the tool 364. An angular displacement sensor, such as an encoder, can also be useful in the configurations of FIGS. 8-9 to determine the amount of rotation of the shaft when only a portion (e.g. 50%) of one revolution is needed. Thus, the depth of insertion can be controlled.
- 10 The controller 360 can also be coupled to external sensors 366 which relay signals to the controller 360. For example, an electrode could be placed immediately adjacent to the site at which the implant is to be inserted. The osteotome tools 364 have a corresponding electrode which is cantilevered from the outer surface of the tool at a point along its length corresponding to the appropriate depth of insertion. When the tool
- 15 is pushed into the bone and the two electrodes touch, a signal is relayed to the controller 360 which stops the drive mechanism. Thus, the depth of insertion is controlled.

The controller 360 could monitor external sensors 366 solely within the tool. For example, the tool may have optical sensors at known points along its length. When an optical sensor enters the bone, the controller 366 senses the exact depth at which the tool

20 has been inserted. Thus, the controller 366 stops the drive mechanism when the optical sensor associated with the desired depth encounters the bone. The optical sensor could be replaced by pressure sensor since the surface of the implant will become stressed when it engages bone.

The controller 360 also is preferably coupled to a clinician input device 368

25 which allows the clinician to select various parameters related to the operation of the drive mechanism 362. For example, the clinician may select the depth of insertion, the frequency of the reciprocation motion, or the amplitude of the reciprocating motion. The clinician input device 368 also includes simple on/off buttons to allow the clinician to turn the drive mechanism 362 on and off.

To further assist in the insertion of the tools, the drive mechanism which remains coupled to the tool (FIGS. 5A-5C) can also provide for a minimal rotation of the tool. Thus, a point along the surface of the tool moves in a helical fashion as it is inserted into the bore and rotated simultaneously. The armature 202 of the solenoid 200 in FIG. 7, the rod 310 of the piezoelectric transducer 300 of FIG. 11, or the rod 324 of the hydraulic driving mechanism 320 of FIG. 13 could be coupled, via gears, to an electric motor to provide this rotation. Alternatively, the cammed driving mechanism of FIG. 9 could be rotated in a direction opposite to the arrow shown causing the corresponding cam drops 254, 262 to engage and allow for this simple rotation. This may require the member 260 to include a ratcheting mechanism to permit its rotation in only one direction so that the member 260 remains non-rotational when undergoing the translation motion. And, the gear configuration of FIG. 8 can also be used to supply rotational movement.

15 Although the tools and driving mechanism have been primarily described with respect to the human jawbone, this technique can be used in nearly all bone tissue. In other words, this technique has applications in surgery where an anchoring device is installed in bone tissue other than when a dental implant is placed in the jawbone.

CLAIMS:

1. A method for developing in living bone a bore that is defined by a bore wall with high-density bone tissue at a region of said wall that is adjacent to an exterior surface of said bone, said method comprising the steps of:
- developing a pilot hole through said exterior surface and into said living bone, said pilot hole being defined by a first wall;
- providing an elongated tool having a central axis, a lower end, an upper end and an engaging surface between said lower and upper ends, said tool having a generally circular cross-section taken perpendicular to said central axis, said cross-section having an area that decreases from said upper end to said lower end, said lower end being dimensioned for insertion into said pilot hole;
- providing a driving mechanism capable of providing movement to said tool;
- coupling said driving mechanism to said upper end of said tool;
- inserting said lower end of said tool into said pilot hole;
- activating said movement of said driving mechanism;
- moving said upper end of said tool toward said pilot hole so that said engaging surface of said tool forces said first wall radially outward with respect to said central axis of said tool to create said bore wall with said high-density bone tissue at said region of said wall that is adjacent to said exterior surface; and
- extracting said tool from said bore with generally no effect on the bone density at said region of said bore wall adjacent to said exterior surface.
2. The method of claim 1 wherein said movement from said driving mechanism imparted to said tool is longitudinal movement along said central axis of said tool and said step of moving said upper end of said tool toward said pilot hole is accomplished through said longitudinal movement.
- 25 3. The method of claim 1 wherein said movement from said driving mechanism imparted to said tool is vibrational movement and said step of moving said upper end of said tool is accomplished through movement provided by a clinician.

4. The method of claim 1 wherein said cross-section of said tool expands rapidly between said lower and upper ends at a transition region, said transition region forcing said first wall radially outward.

5. The method of claim 1 wherein said cross-section of said tool expands gradually between said lower and upper ends.

6. The method of claim 1, further including the steps of:
providing a second elongated tool having a central axis, a bottom end, a top end and an engaging surface between said top and bottom ends, said second tool having a generally circular cross-section taken perpendicular to said central axis that decreases from said top 10 end to said bottom end, said bottom end having a cross-sectional area that is approximately no larger than said upper end of said first elongated tool;

coupling said driving mechanism to said top end of said second tool;
inserting said bottom end of said second tool into said bore;
initiating said movement of said driving mechanism;
15 moving said top end of said second tool toward said pilot hole so that said engaging surface of said second tool further creates said high-density bore wall; and
extracting said second tool from said bore with generally no effect on the bone density at said region of said bore adjacent to said exterior surface.

7. The method of claim 6 wherein said cross-section of said first tool expands 20 rapidly between said lower and upper ends at a transition region, said transition region forcing said first wall radially outward, said cross-section of said second tool expands gradually between said top and bottom ends.

8. The method of claim 1 further including the step of removing a portion of 25 said bone tissue at said first wall and displacing said bone tissue in a direction away from said exterior surface of said bone.

9. The method of claim 8 wherein said lower end of said tool is dimensioned to be slightly larger than said pilot hole and said tool includes a section for gathering said bone tissue to be displaced.

10. A method for developing in living bone a bore defined by a bore wall with 30 high-density bone tissue along a substantial portion of a length of said bore wall, said living

bone having an internal wall defining an initial hole at the site where said bore is to placed, said method comprising the steps of:

- providing an elongated tool having a central axis, a lower end, an upper end and an engaging surface between said lower and upper ends, said engaging surface having a sequence of regions from said lower end to said upper end that increase in cross-sectional area;
- 5 providing a driving mechanism capable of providing longitudinal movement; coupling said driving mechanism to said upper end of said tool such that said longitudinal movement is substantially in the direction of said central axis of said tool;
- 10 inserting said lower end of said tool into said initial hole;
- activating said longitudinal movement of said driving mechanism to move said upper end of said tool toward said initial hole so that sections of said internal wall of said initial hole is progressively acted upon by said sequence of regions of increased cross-sectional area to create said high-density bone tissue along said substantial portion of said 15 length of said bore wall; and
- extracting said tool from said bore wall.

11. The method of claim 10 wherein said step of extracting said tool removes only an insubstantial amount of bone tissue from said bore.

12. The method of claim 10 wherein said step of extracting said tool 20 insubstantially affects said high-density bone tissue of said bore wall.

13. The method of claim 10 wherein said step of activating said longitudinal movement includes the step of removing a portion of the bone tissue on said internal wall with said tool and displacing said portion in a direction away from an opening of said bore.

14. The method of claim 10 wherein said tool tapers gradually to provide said 25 sequence of regions on said engaging surface.

15. The method of claim 10 wherein said tool expands in cross-section rapidly between said lower and upper ends at a transition region, portions of said engaging surface on either side of said transition region and said transition region providing said sequence of regions on said engaging surface.

16. The method of claim 10 wherein said initial hole is created by another tool.
17. The method of claim 16 wherein said another tool is a compaction tool similar to said elongated tool.
18. The method of claim 10 wherein said bore is to be developed in a jawbone, 5 said internal wall is a lower-density Type III or Type IV bone tissue and said high-density bone tissue is comparable to Type I or Type II bone tissue.
19. A method for developing in living bone a bore defined by a bore wall with high-density bone tissue along a substantial portion of a length of said bore wall, said living bone having an internal wall defining an initial hole at the site where said bore is to be 10 placed, said method comprising the steps of:
- providing an elongated tool having a central axis, a lower end, an upper end and an engaging surface between said lower and upper ends, said engaging surface having a sequence of regions from said lower end to said upper end that increase in cross-sectional area;
- 15 providing a driving mechanism capable of providing vibrational movement; coupling said driving mechanism to said upper end of said tool; inserting said lower end of said tool into said initial hole; actuating said vibrational movement of said driving mechanism; moving said upper end of said tool toward said initial hole so that said sequence of 20 regions of said engaging surface progressively act upon and force said internal wall of said initial hole radially outward with respect to said central axis to create said high-density bone tissue along said substantial portion of said length of said bore wall; and extracting said tool from said bore.
20. The method of claim 19 wherein said vibrational movement is substantially 25 in the direction of said central axis of said tool.
21. The method of claim 19 wherein said steps of actuating said vibrational movement and moving said upper end of said tool occur simultaneously.
22. The method of claim 19 wherein said driving mechanism is further capable 30 of providing longitudinal motion, said step of moving said upper end of said tool toward said initial hole is accomplished by said driving mechanism.

23. The method of claim 19 wherein said step of moving said upper end of said tool toward said initial hole is accomplished through manual exertion of force by a clinician.

24. The method of claim 19 wherein said initial hole is created by another tool.

5 25. The method of claim 19 wherein said step of extracting said tool removes only an insubstantial amount of bone from said bore.

26. The method of claim 19 further including the step of removing a portion of the bone tissue from said internal wall of said initial bore and displacing said portion in a direction away from an opening of said bore.

10 27. The method of claim 19 wherein said tool tapers gradually to provide said sequence of regions on said engaging surface.

28. The method of claim 19 wherein said tool expands in cross-section rapidly between said lower and upper ends at a transition region, portions of said engaging surface on either side of said transition region and said transition region providing said sequence of regions on said engaging surface.

15 29. The method of claim 19 wherein said bore is to be developed in a jawbone, said internal wall is a lower-density Type III or Type IV bone tissue and said high-density bone tissue is comparable to Type I or Type II bone tissue.

30. A combination of a set of tools and a driving mechanism for creating in living bone a bore that is defined by a bore wall with high-density bone tissue, said set of tools for compacting bone tissue on said bore wall, said set including a plurality of tools each having a central axis, a lower end, an upper end and an engaging surface between said lower and upper ends, said tool having a generally circular cross-section taken perpendicular to said central axis, said cross-section having an area that decreases from said upper end to said lower end, said engaging surface being configured to maintain substantially all of said bone within said bore when said tool is extracted therefrom, said set of tools including at least one tool having a larger cross-sectional area adjacent to said lower end than said remaining ones of said set of tools; and

30 said driving mechanism including means for interchangeably coupling said driving mechanism to said upper end of a selected tool of said set of tools, said driving mechanism

further including means for providing longitudinal movement to said selected tool of said set of tools.

31. The combination of claim 30 wherein said coupling means includes means for quickly releasing and attaching said selected one of said set of tools from said driving mechanism.

32. The combination of claim 31 wherein said coupling means includes a spring element.

33. The combination of claim 31 wherein said coupling means includes a pin element extending into said tool.

10 34. The combination of claim 30 wherein said longitudinal movement providing means includes a cam element.

35. The combination of claim 30 wherein said longitudinal movement providing means includes a pair of meshing gears.

15 36. The combination of claim 30 wherein said longitudinal movement providing means includes a solenoid.

37. The combination of claim 30 wherein said longitudinal movement providing means includes a piezoelectric element.

38. The combination of claim 30 wherein said set of tools includes at least one tool that expands rapidly between said lower and upper ends at a transition region.

20 39. The combination of claim 30 wherein each of said set of tools includes marking means positioned a common distances from said lower end.

40. The combination of claim 39 wherein said marking means includes a groove.

25 41. The combination of claim 39 wherein said marking means includes a ring positioned around said tool.

42. The combination of claim 30 wherein at least one of said tools includes an inwardly concave lower end.

43. The combination of claim 30 wherein at least one of said tools includes an outwardly convex lower end.

44. A combination of a set of tools and a driving mechanism for creating in living bone a bore defined by a bore wall that has high-density bone tissue, said set of tools for compacting bone tissue on said bore wall, said set including a plurality of tools each having a central axis, a lower end, an upper end and an engaging surface between said lower and upper ends, said engaging surface having a sequence of regions from said lower end to said upper end that increase in cross-sectional area, said engaging surface being configured to maintain substantially all of said bone within said bore when said tool is extracted therefrom, said set of tools including at least one tool having a larger cross-sectional area adjacent to said lower end than said remaining ones of said set of tools; and

10 said driving mechanism including means for interchangeably coupling said driving mechanism to said upper end of a selected tool of said set of tools, said driving mechanism further including means for providing vibrational movement to said selected tool of said set of tools.

45. The combination of claim 44 wherein said vibrational movement is primarily in the direction of said central axis of said tool.

46. The combination of claim 44 wherein said tool tapers gradually to provide said sequence of regions on said engaging surface.

47. The combination of claim 44 wherein said tool expands in cross-section rapidly between said lower and upper ends at a transition region, portions of said engaging surface on either side of said transition region and said transition region providing said sequence of regions on said engaging surface.

48. The combination of claim 44 further including a structure that allows the clinician to grasp to manually push said tool into said bore.

49. The combination of claim 44 wherein said vibrational movement providing means includes a piezoelectric element.

50. A combination of a set of tools and a driving mechanism for creating in living bone a bore that has high-density bone tissue, said set of tools including a plurality of tools each having a central axis, a lower end, and an upper end, each of said set of tools having a cutting edge exclusively at said lower end, said set of tools including at least one

tool having a larger cross-sectional area adjacent to said lower end than said remaining ones of said set of tools; and

5 said driving mechanism including means for interchangeably coupling said driving mechanism to said upper end of a selected tool of said set of tools, said driving mechanism further including means for moving said selected tool of said set of tools.

51. The combination of claim 50 wherein said moving means provides vibrational movement.

52. The combination of claim 50 wherein said moving means provides longitudinal movement.

10 53. The combination of claim 50 wherein each of said tools includes means for transferring bone tissue from regions in said bore near an exterior surface of said bone to deeper regions of said bore.

54. The combination of claim 53 wherein said transferring means is a concave face at said lower end of said tool.

15 55. The combination of claim 54 wherein cutting surface is defined by the interface of said concave face and said engaging surface at said lower end.

56. The combination of claim 50 wherein said set of tools includes a tool for making a small-diameter pilot hole, one of said set of tools having a diameter at said lower end that is slightly larger than said pilot hole.

20 57. A combination of a set of tools and a driving mechanism for creating in living bone a bore that defined by a bore wall having high-density bone tissue, said set including a plurality of tools each having a central axis, a lower end, an upper end and a bone-engaging surface between said lower and upper ends, said bone-engaging surface for compacting bone tissue on said bore wall to create said high-density bone tissue; and

25 said driving mechanism including means for interchangeably coupling said driving mechanism to said upper end of a selected tool of said set of tools, said driving mechanism further including means for imparting non-rotational movement to said selected tool of said set of tools.

58. The combination of claim 57 wherein said movement imparting means provides primarily vibrational movement.

59. The combination of claim 57 wherein said movement imparting means provides primarily longitudinal movement.

60. The combination of claim 57 wherein said bone-engaging surface extends substantially the entire distance between said lower and upper surfaces.

5 61. A method for transferring bone tissue from a section of a bore to a deposit region of said bore, said bore being defined by a bore wall, said method comprising the steps of:

10 providing an elongated tool having a lower end, an upper end, a cutting edge adjacent to said lower end, and a gathering section adjacent to said cutting edge for receiving said bone tissue to be transferred,

15 providing a driving mechanism capable of providing movement to said tool; coupling said driving mechanism to said upper end of said tool; inserting said lower end of said tool into said bore; moving said upper end of said tool said bore so that said cutting edge of said tool removes said bone tissue from said bore wall while said driving mechanism is providing said movement to said tool;

20 collecting said removed bone tissue in said gathering section; continuing moving said tool into said bore; depositing said removed bone tissue at said deposit region of said bore; and extracting said tool from said bore after said gathering section has reached said deposit region of said bore.

62. The method of claim 61 wherein said step of moving said upper end of said tool is accomplished through movement provided by a clinician, said movement provided by said driving mechanism being primarily vibrational movement.

25 63. The method of claim 61 wherein said movement is primarily longitudinal movement and said step of moving said upper end of said tool is accomplished through said longitudinal movement provided by said driving mechanism.

64. The method of claim 61 wherein said gathering section is an inwardly concave face at said lower end.

65. The method claim 64 wherein said cutting edge is exclusively at a lowermost portion of said lower end.

66. The method of claim 61 wherein said depositing region is located at the deepest region of said bore.

5 67. The method of claim 61 further including the step of compacting bone tissue on said bore wall with a bone-engaging surface between said upper and lower ends.

68. The method of claim 67 wherein said bore is to be inserted in a jawbone and said step of compacting results in a high-density bore wall of Type I or Type II bone tissue.

10 69. A system for creating in living bone a bore that defined by a bore wall having high-density bone tissue, said system comprising:

a tool having a central axis, a lower end, an upper end and a bone-engaging surface between said lower and upper ends, said bone-engaging surface for compacting bone tissue on said bore wall to create said high-density bone tissue;

15 a driving mechanism including means for interchangeably coupling said driving mechanism to said upper end of said tool, said driving mechanism imparting movement to said tool;

means for sensing a characteristic of said tool, said sensing means producing signals; and

20 a controller coupled to said driving mechanism and said sensing means, said controller controlling the operation of said driving mechanism in response to said signals received from said sensing means.

70. The system of claim 69 wherein said movement is primarily vibrational movement.

71. The system of claim 69 wherein said movement is primarily longitudinal movement.

72. The system of claim 69 wherein said characteristic is a movement characteristic of said tool and said sensing means is a movement sensor.

73. The system of claim 69 wherein said characteristic is a positional characteristic of said tool and said sensing means is a position sensor.

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74. The system of claim 69 wherein said sensing means is mounted on said tool.

75. The system of claim 69 wherein said sensing means is mounted on said driving mechanism.

5 76. The system of claim 69 wherein said sensing means is mounted externally to said tool and said driving mechanism.

77. The system of claim 69 further including means for inputting operational characteristics of said tool by said clinician, said inputting means being coupled to said controller.

10 78. The system of claim 69 wherein said characteristic is operational frequency.
79. The system of claim 69 wherein said characteristic is operational amplitude.

80. A combination of a set of tools and a driving mechanism for creating in living bone a bore that has high-density bone tissue, said set of tools including a plurality of tools each having a central axis, a lower end, and an upper end, each of said set of tools including means for delivering a material to a region of said bore, said set of tools including at least one tool having a larger cross-sectional area adjacent to said lower end than said remaining ones of said set of tools; and

15 said driving mechanism including means for interchangeably coupling said driving mechanism to said upper end of a selected tool of said set of tools, said driving mechanism further including means for moving said selected tool of said set of tools.

20 81. The combination of claim 80 wherein said delivering means includes an internal channel within said tool.

82. The combination of claim 80 wherein said delivering means includes an opening on an exterior surface of said tool.

25 83. The combination of claim 80 wherein said delivering means includes a pumping source to convey said material to said tool.

84. The combination of claim 80 wherein said material is an osseointegration enhancing materials.

85. The combination of claim 80 wherein said material is a lubricating material.

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86. A combination of a compaction tool and a driving mechanism for creating
in living bone a bore that has high-density bone tissue, said compaction tool having a
central axis, a lower end, an upper end, and an engaging surface between said lower end
and said upper end, said engaging surface for displacing bone tissue that is initially in the
5 area defined by said bore primarily in the radial direction to said central axis; and
said driving mechanism including means for interchangeably coupling said driving
mechanism to said upper end of said tool, said driving mechanism further including means
for moving said tool.
87. The combination of claim 86 wherein said moving means provides
10 vibrational movement.
88. The combination of claim 86 wherein said moving means provides
longitudinal movement.
89. The combination of claim 86 wherein said combination is for use in a
jawbone and said engaging surface is configured to compact lower-density Type III or
15 Type IV bone tissue to Type I or Type II bone tissue.

ABSTRACT

The invention set forth includes a set of tools which compact bone tissue as they develop a bore in the bone tissue and a driving mechanism for providing movement to the tools. The tools have engaging surfaces which displace bone tissue radially outward with respect to a central axis of the tool to create high density bone tissue at the wall defining the bore. The driving mechanism may provide only vibrational movement to assist in inserting the tool. Alternatively, the driving mechanism may provide translational movement in the longitudinal direction with respect to the tool to insert the tool into the bone.

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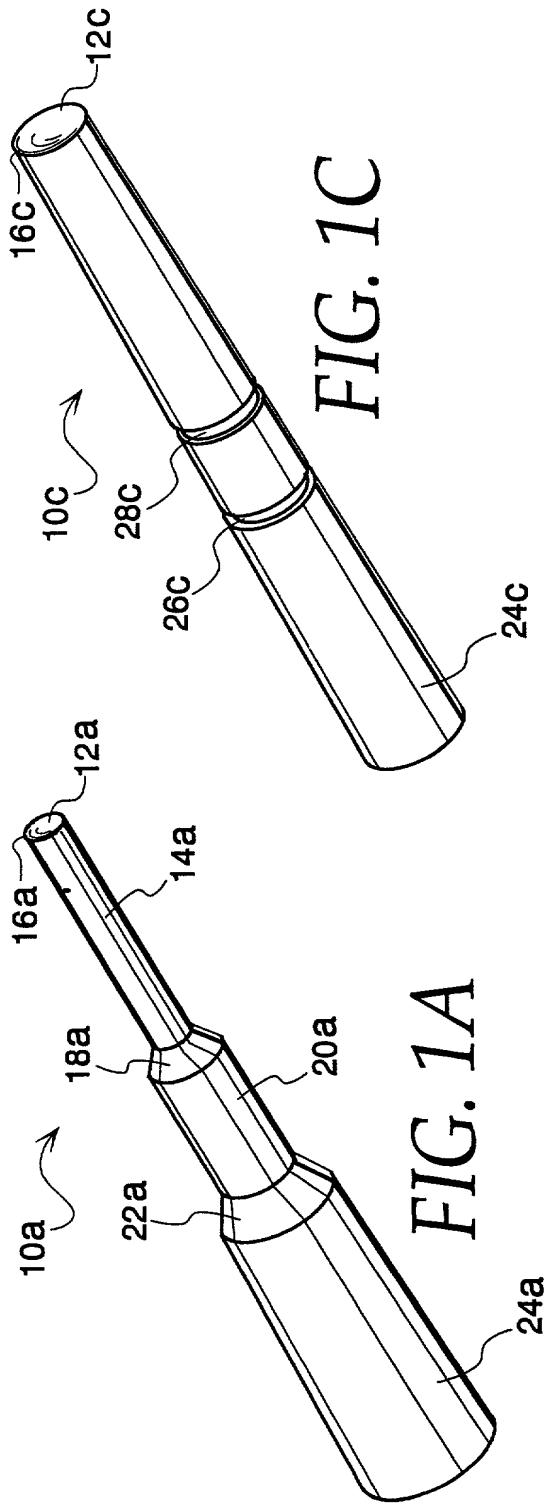


FIG. 1C

FIG. 1A

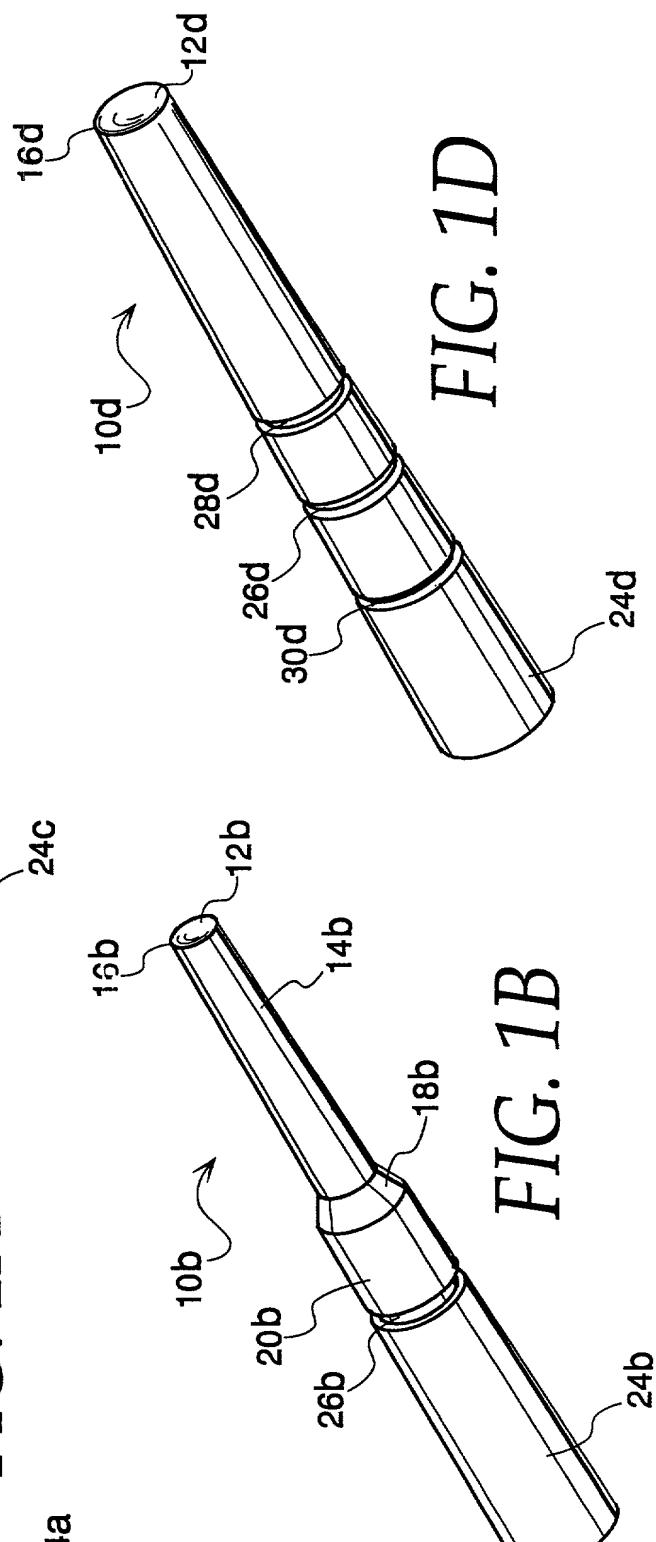
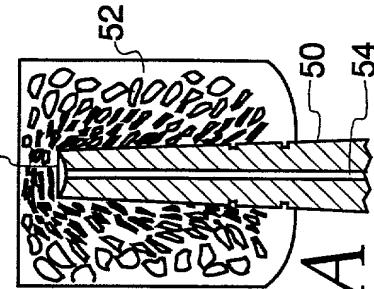
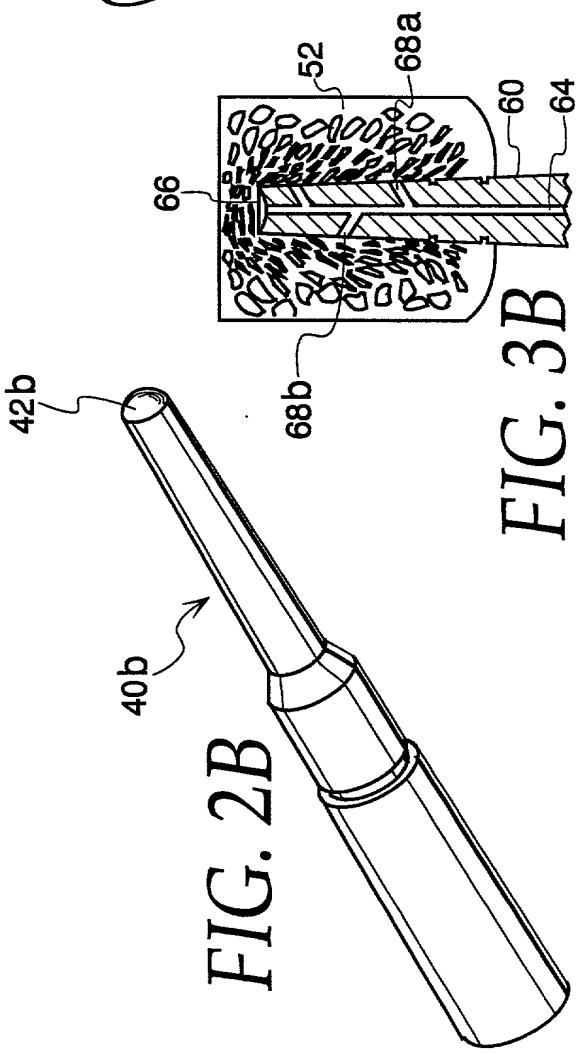
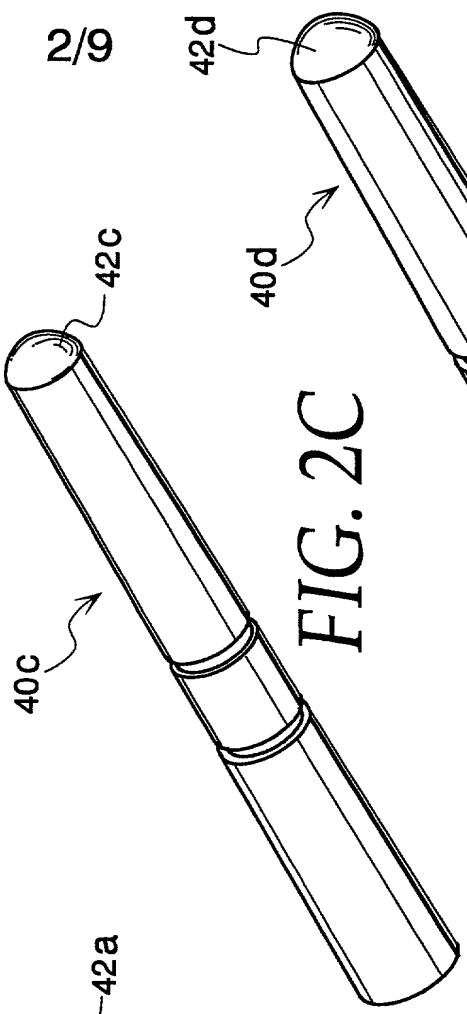
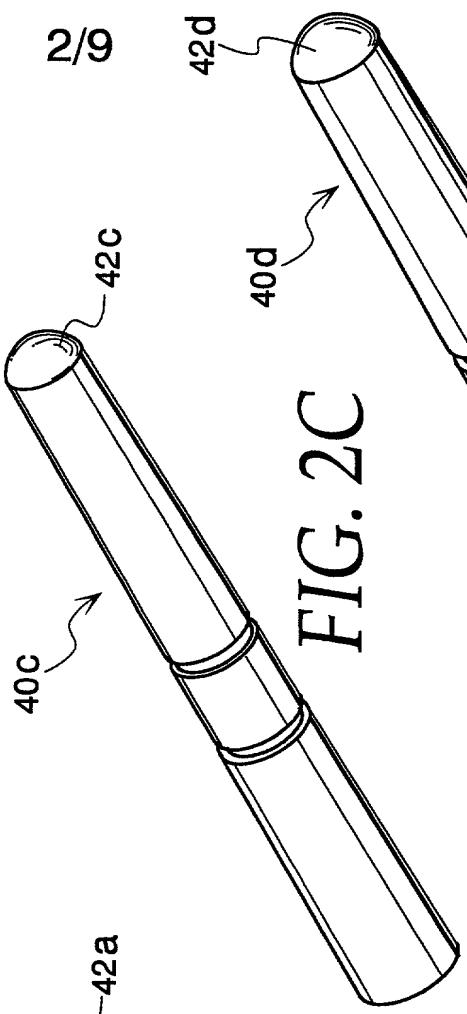
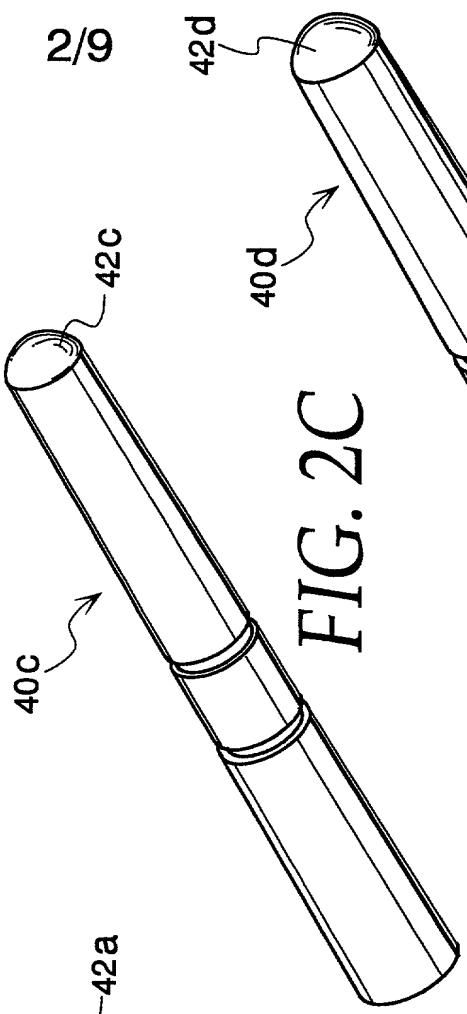
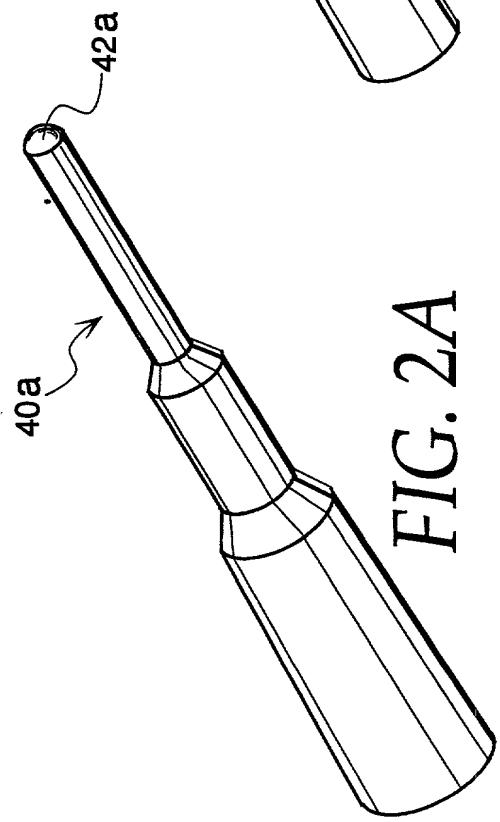


FIG. 1B

FIG. 1D

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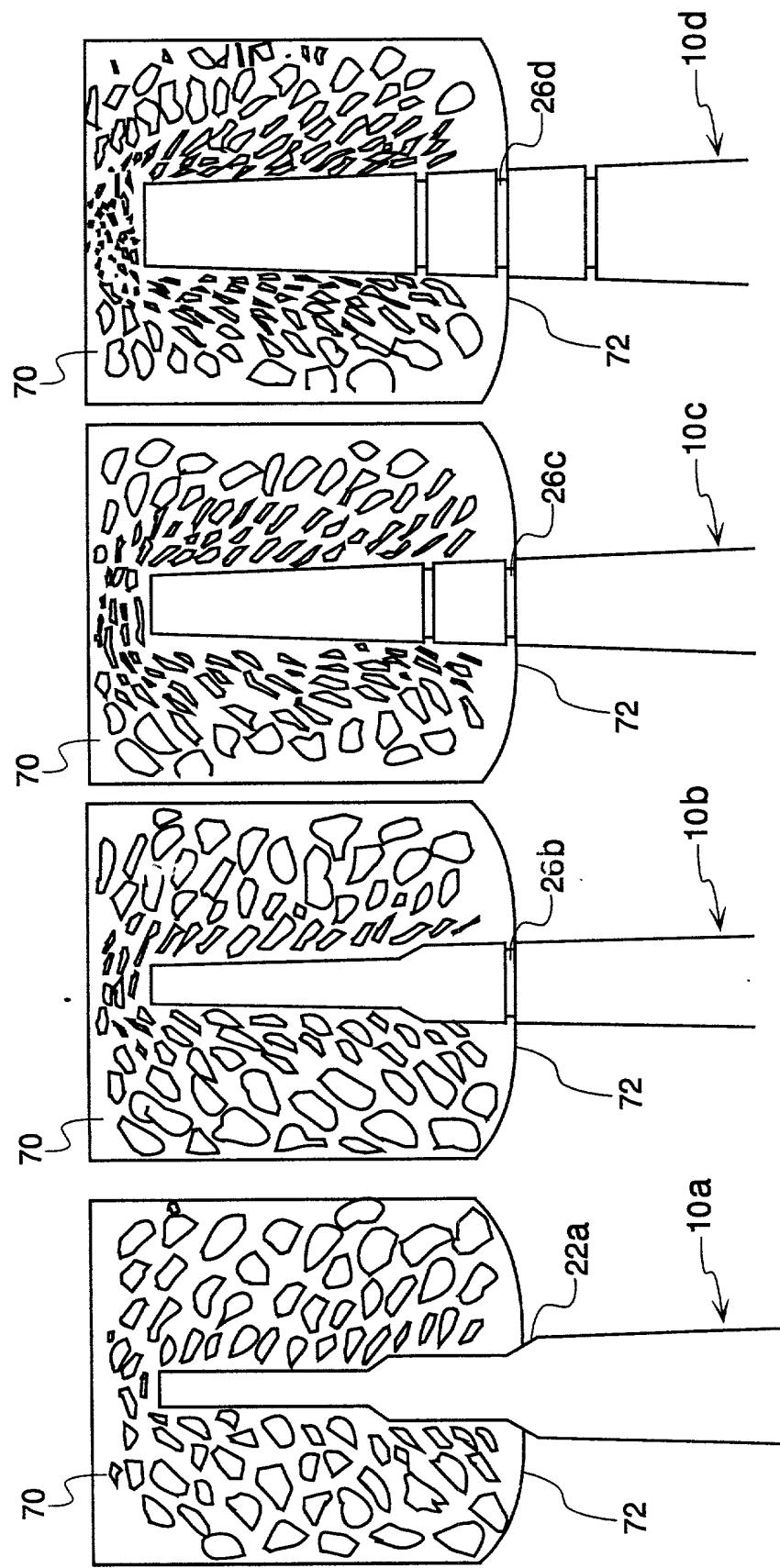
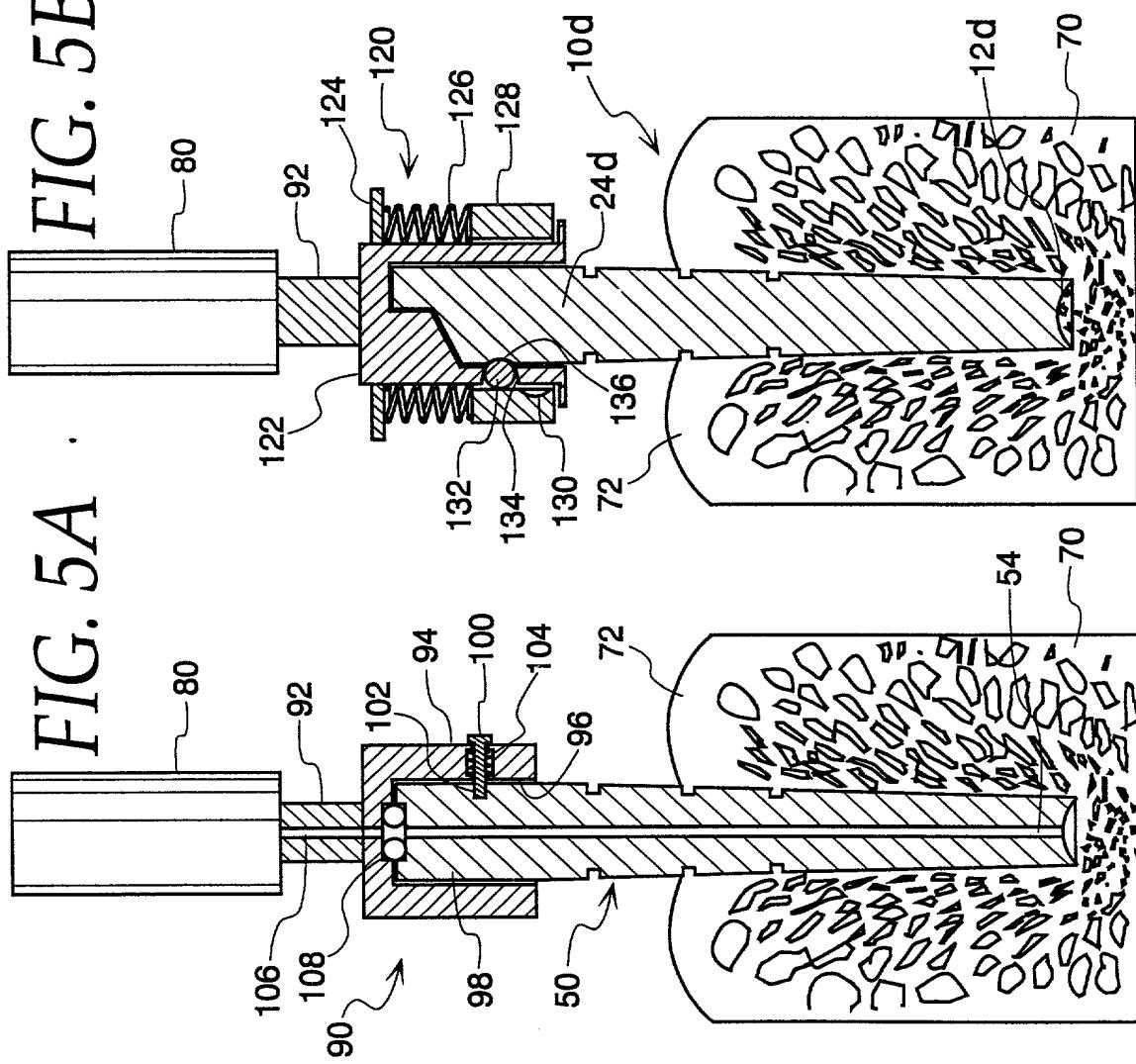
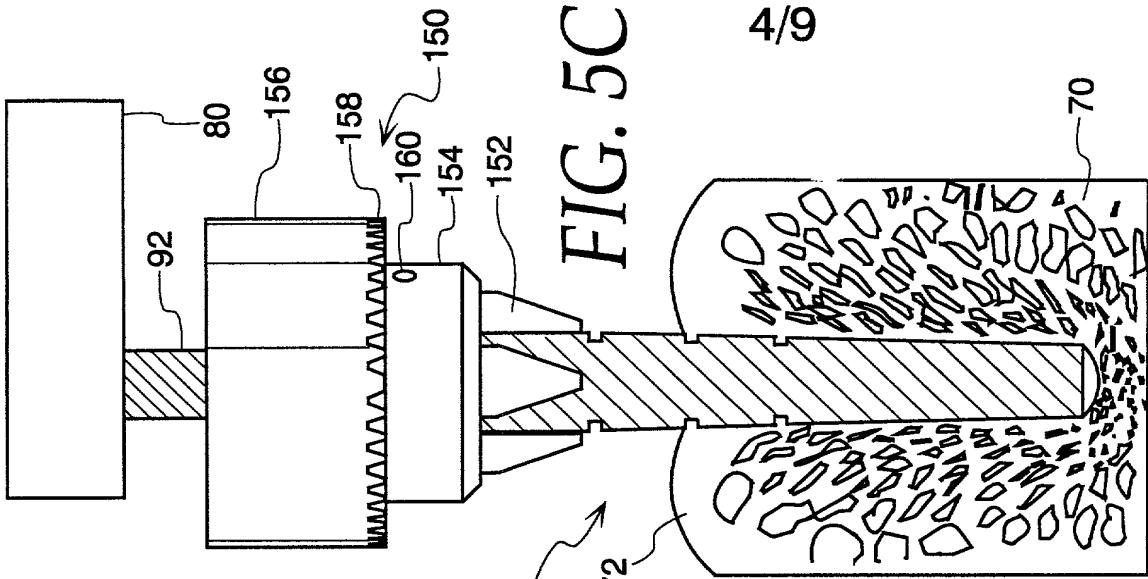
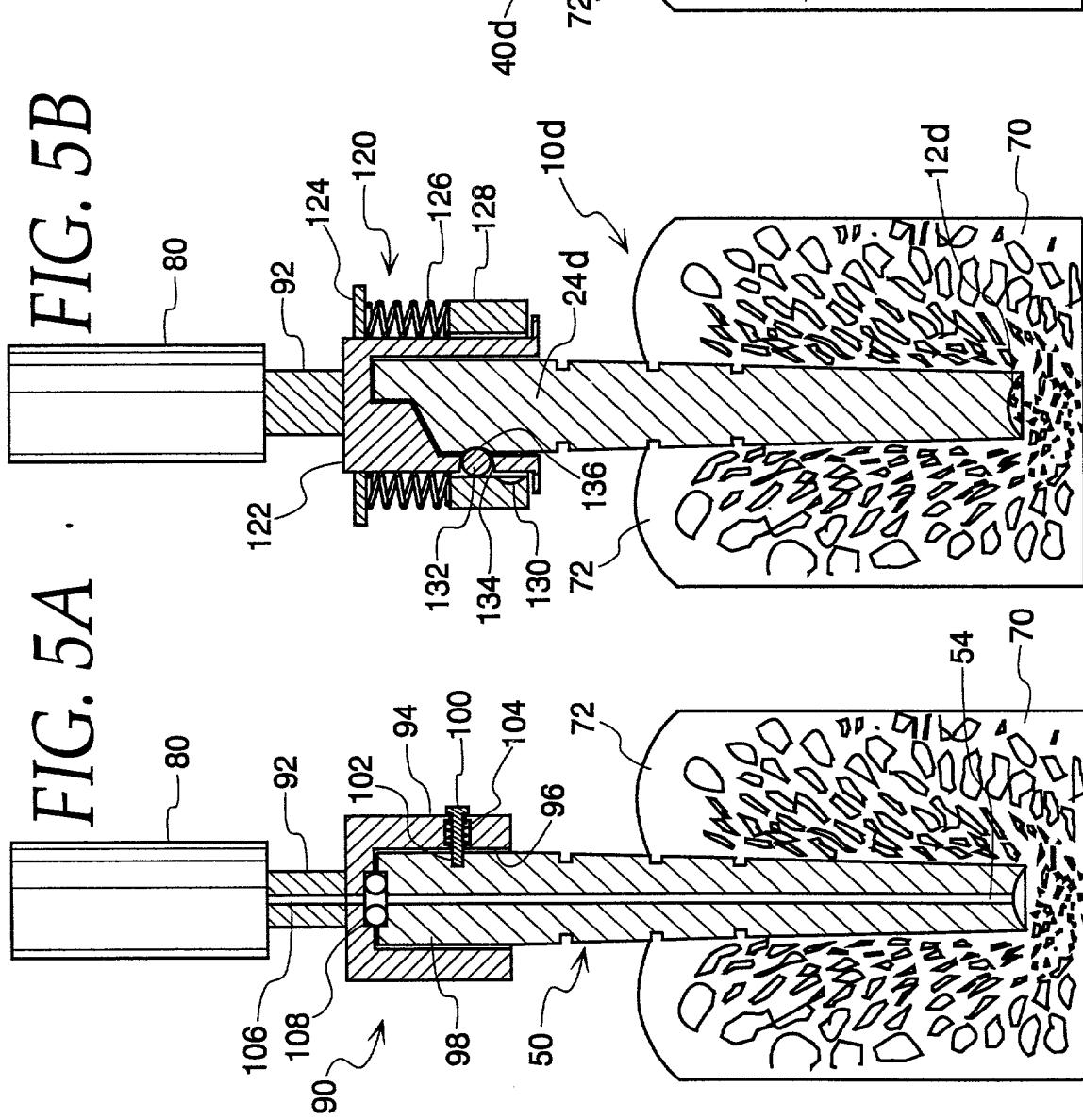


FIG. 4A FIG. 4B FIG. 4C FIG. 4D 3/9



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FIG. 6A

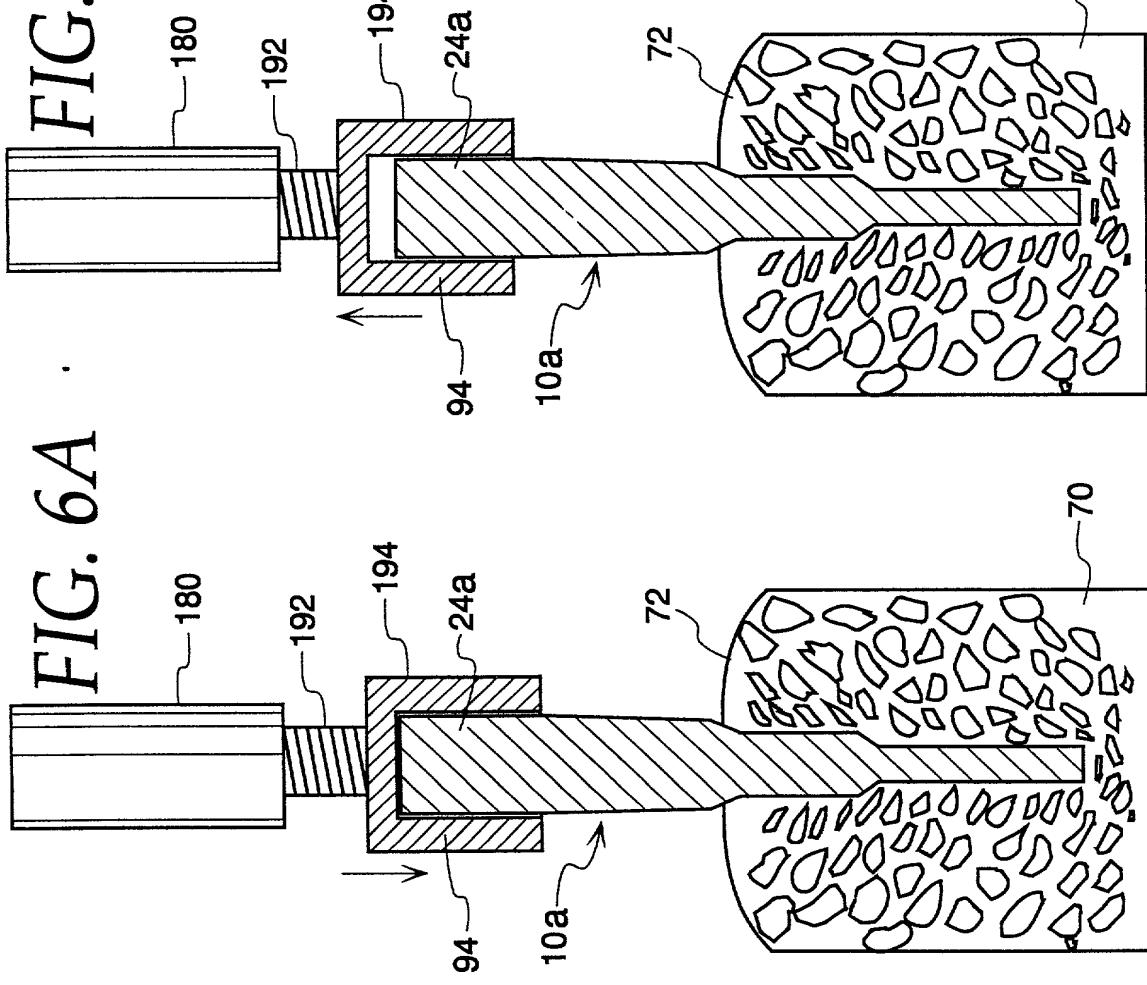


FIG. 6B

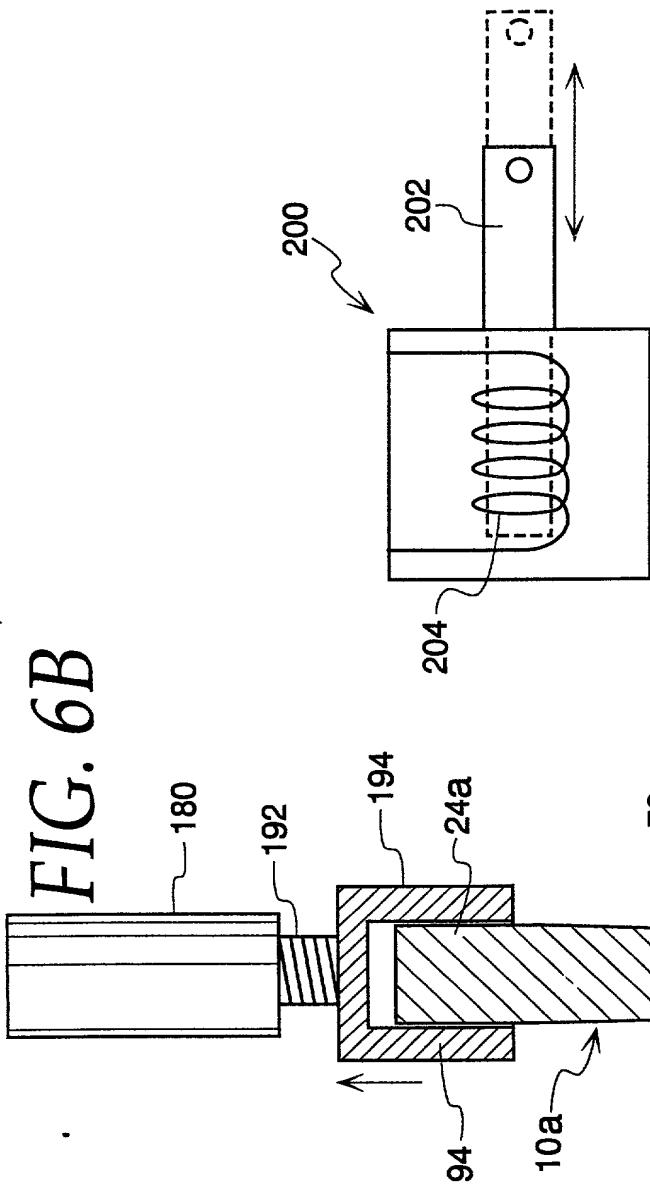
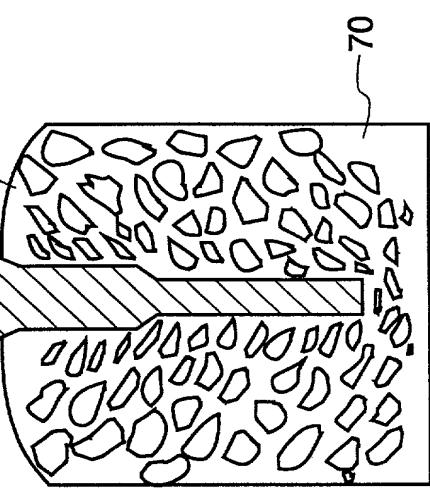


FIG. 7

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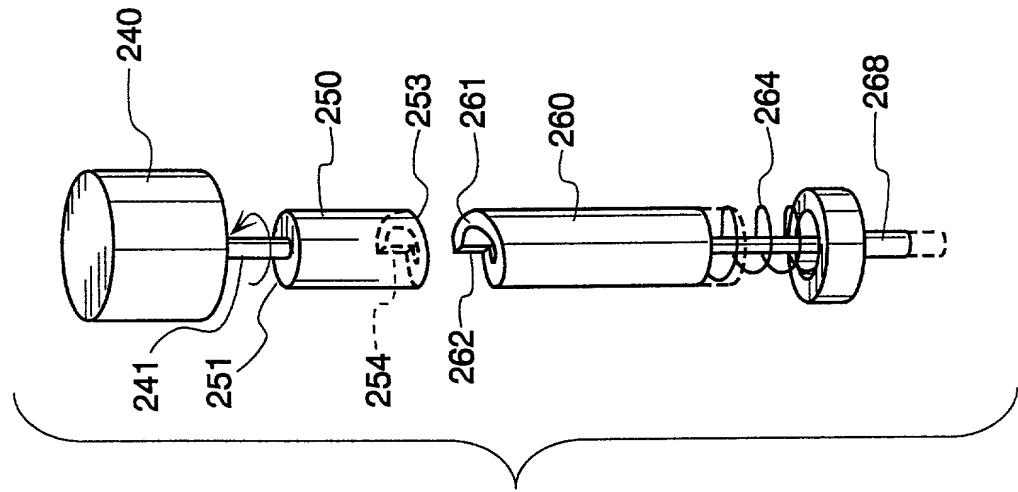


FIG. 9

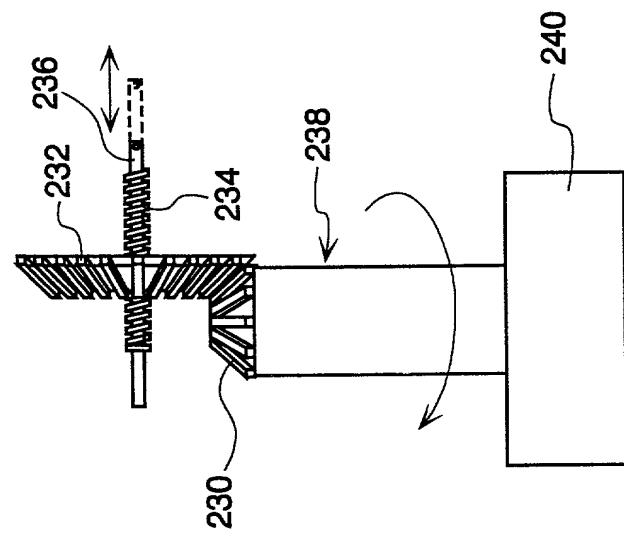
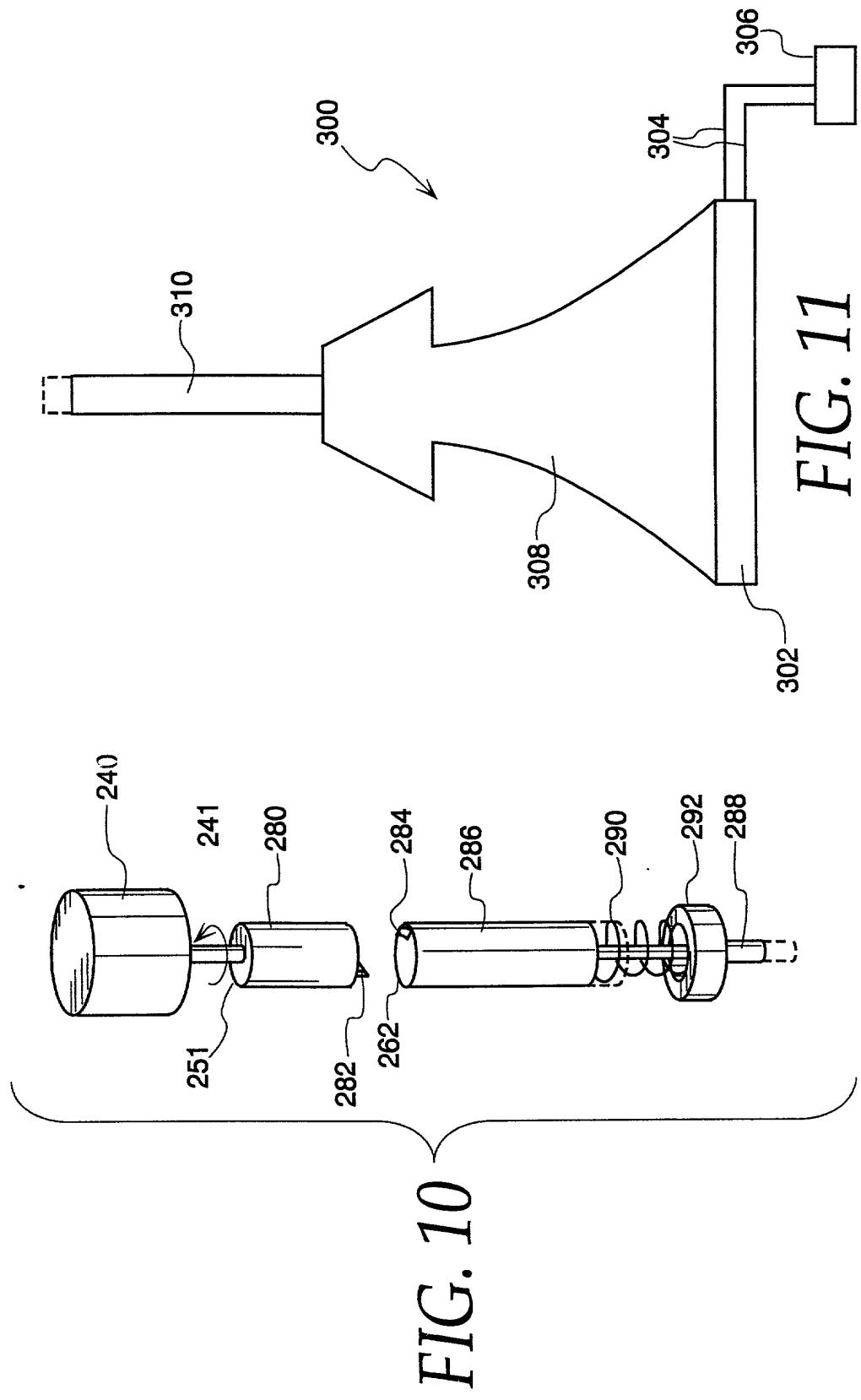


FIG. 8

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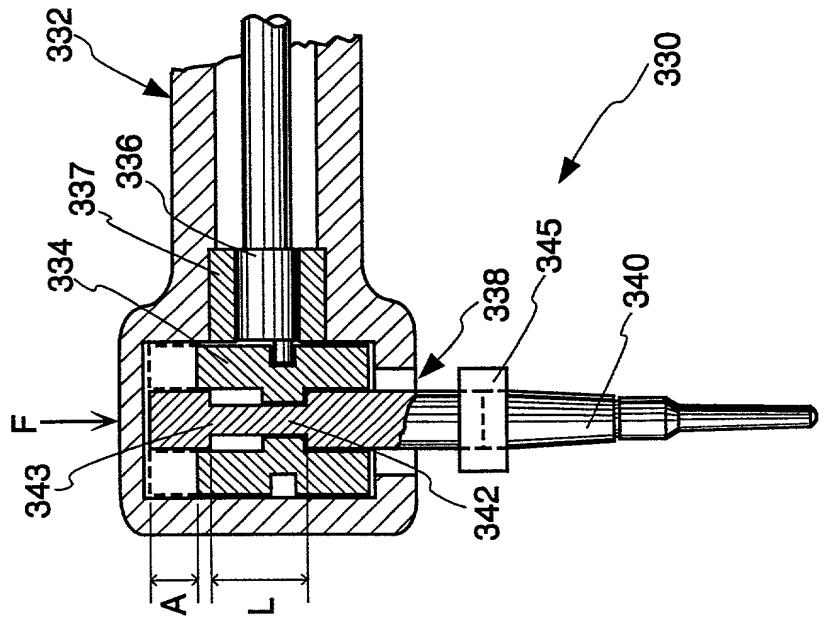


FIG. 13

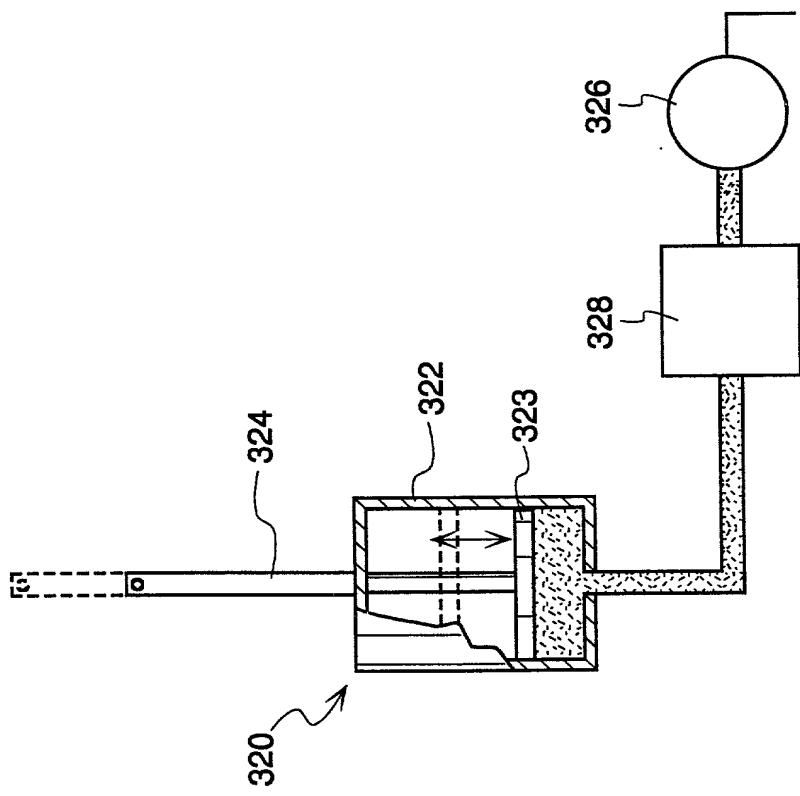


FIG. 12

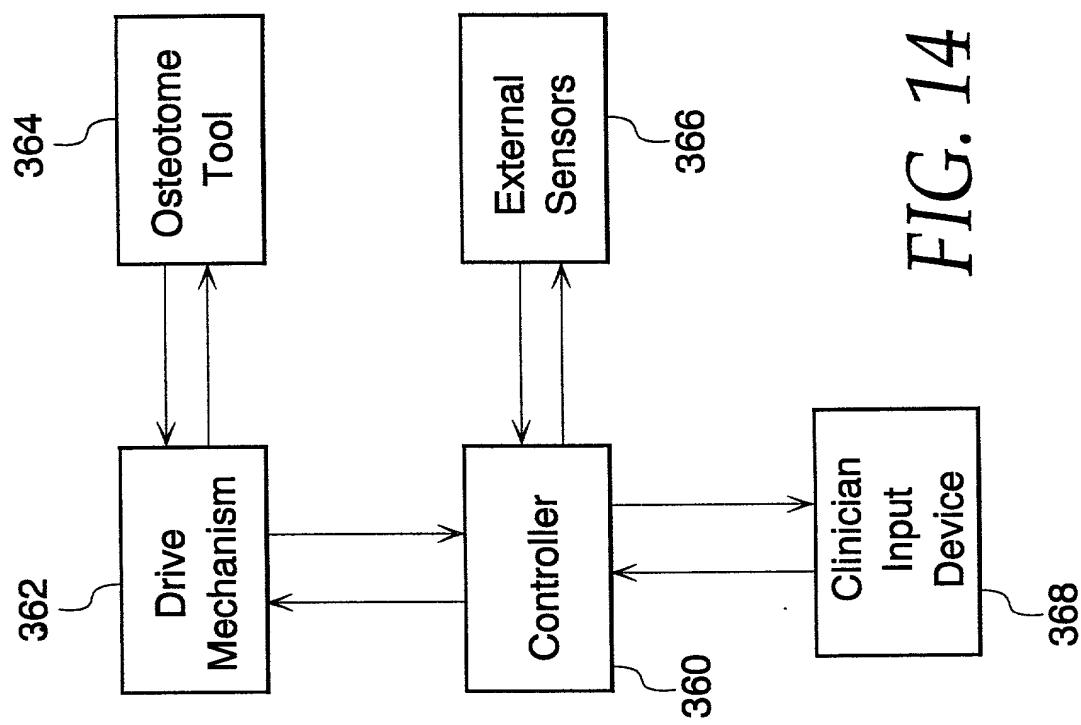


FIG. 14

DECLARATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe the below named inventors are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled **POWER-DRIVEN OSTEOTOME TOOLS FOR COMPACTION OF BONE TISSUE**, the specification of which:

- is attached hereto.
 was filed on _____ as Application Serial No. _____

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

**PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN)
PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. §119(a)-(d)**

I hereby claim foreign/PCT priority benefits under Title 35, United States Code, §119 of any foreign/PCT application(s) for patent or inventor's certificate listed below and have also identified below any foreign/PCT application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

| PRIOR FOREIGN/PCT APPLICATION(S) | <u>Priority Claimed</u> |
|----------------------------------|-------------------------|
| (Number) | Yes/No |
| (Country) | |
| (Date Filed) | |

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (35 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

| | | |
|--------------------------|---------------|----------|
| 60/022,148 | July 18, 1996 | Expired |
| (Application Serial No.) | (Filing Date) | (Status) |

CLAIM FOR BENEFIT OF PRIOR U.S. APPLICATION(S) (35 U.S.C. § 120)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a), regarding events which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

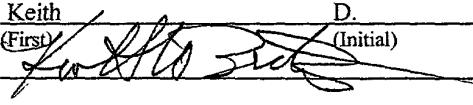
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|--------------------------|---------------|----------|
| PCT/US97/12512 | July 17, 1997 | Pending |
| (Application Serial No.) | (Filing Date) | (Status) |

I hereby direct that all correspondence and telephone calls be addressed to Stephen G. Rudisill, Esq., Arnold, White & Durkee, P.O. Box 4433, Houston, Texas 77210, (312) 744-0090.

ARNOLD; WHITE & DURKEE

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Inventor's Full Name: Keith D. Beaty
(First) (Initial) (Last)

Inventor's Signature: 

Date: 1/12/99 Country of Citizenship: U.S.A.

Residence: 16 Riverside Drive West, Jupiter, FL 33469-2960 U.S.A.
(Include number, street name, city, state, and country)

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